CURRICULUM VITAE

Ernest Opoku-Agyemang, PhD, MA, RN

EDUCATION & HONORS

- PhD, Univ. of Maryland, Baltimore, December 2020
- MSN (Informatics), Univ. of Maryland, Baltimore, (May 2012)
- BSN, University of Maryland, Baltimore, May 2010.
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- MS Information Systems, UMUC (1999 – 2001, 27 credits (did not graduate, transferred credits)
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- B.Sc.(Honors) Land Economy, University of Science & Tech., Ghana (June 1994)

AWARDS AND PROFESSIONAL AFFILIATIONS

- Recipient: Nurse Corps Loan Repayment Program for Nurse Faculty (2016 – 2019)
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- Recipient: Murray Foundation Scholarship for Nursing Students Montgomery College (2006/07)
- Recipient: British Government Merit Scholarship, University of Hull, UK (1996/97).
- Recipient: Advanced Education Nursing Traineeship, University of Maryland, (2011/2012).
- Dean’s List: Montgomery College, 2004 to 2005
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LICENSURE & PROFESSIONAL CERTIFICATION

- RN License, Maryland and DC, Active
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- MCSE, Microsoft Corp, 2000
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PROFESSIONAL EXPERIENCE: Teaching

University of Maryland, Baltimore – School of Nursing
Clinical Instructor: Nov 2014 – Present

- Teach graduate and undergraduate courses

Service

- Course Director: Healthcare Delivery Systems & Informatics for undergraduates
- Advisor to students on NI Master's Scholarly Papers (2016 – present)
- Advisor to thirteen (22) MS Nursing Informatics students (current)
- Member of BSN Judicial committee (2019 – present)
- Professional advisor - Student Success Center (SSC): Entry-into-practice students (Informatics)
- Member of Technology and Simulation Advisory Committee (2016 – 2018)
- Member of Entry Level Curriculum Committee (2015 – present)
- Member of Planning/Executive Committee: Summer Institute of Nursing (2015 – present)
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Kwame Nkrumah University of Science & Tech., Kumasi, Ghana
Teaching Assistant, Teaching Assistant: 1994 to 1996

- Taught Advance Valuation methods to 3rd and 4th year students.
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Scholarship/Research Interest
Doctoral dissertation research: Development and Usability Testing of a Mobile Health Game Application for Older Adults on Warfarin

PROFESSIONAL EXPERIENCE: Information/Systems Analyst

Clinical Systems Analyst: Concept Plus, LLC, Fairfax, VA
October 2012 - 2014
Senior Software Tester: Client Services Network, Inc. (CNSI). Gaithersburg.
August 2011 – October 2012
Clinical Reporting Analyst: XLHealth Corp, Baltimore, MD
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Quality Assurance Engineer: Thompson Financial, Rockville, MD
December 2006-December 2007
Information Systems Analyst: EDS/NASD, Rockville, MD
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PROFESSIONAL EXPERIENCE: Clinical/Patient Care

Registered Nurse (Clinical Experience): Direct Patient Care

- Med/Surg: Shady Grove Hospital, Rockville, MD, January 2007 to Feb 2009 (Full-Time).
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- **Med/Surg:** Contemporary Nursing (RN Staffing Agency), Baltimore, March 2008 to Dec 2008.
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VOLUNTEER EXPERIENCE

- Student volunteer - Summer Institute of Nursing Informatics (SINI) 2014
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PRESENTATIONS/CONFERENCES

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Scholarly/Unpublished Work

- Doctoral (PhD) dissertation research: Development and Usability Testing of a Mobile Health Game for Older Adults on Coumadin.
- Unpublished manuscript: Development and Usability Testing of a Mobile Health Game for Older Adults on Coumadin. In progress - preparing manuscript for publication.
- Abstract presentation – SINI 2021: Development and Usability Testing of a Mobile Health Game for Older Adults on Coumadin. In progress - preparing abstract presentation for SINI 2021

Abstract

Background: Chronic disease management constitutes a special challenge in the United States due to deficiencies in the healthcare system. Chronic disease self-management (CDSM) using technology and gaming principles is a promising way to overcome these challenges. Yet, there are few disease-specific apps to benefit the populations likely to benefit from such innovations.

Purpose: This proof of concept study evaluated the feasibility of a Warfarin game app for older adults. The aims were to: 1) Design and develop a mobile game app to educate patients on Warfarin; and 2) Conduct usability testing of the game app among patients on Warfarin receiving care at an anticoagulation clinic.

Methods: Following the design and development of a Warfarin app called Coumadin Hero, the usability testing of the app was conducted with 25 participants. Heuristics and user testing were conducted. The Technology Acceptance Model (TAM) was the theory that informed the study design and implementation. An adaptation of the Perceived Health Web Site Usability Questionnaire (PHWSUQ) was used to assess the participant usability. Descriptive and correlational statistics were used to analyze game play data and responses to survey questionnaires.

Results: The median percent correct of Vitamin K food identification was 79%. Generally, participants had higher knowledge of Vitamin K levels in green vegetables (92% - 96%). User technology experience and demographic characteristics were not associated with Vitamin K food knowledge or level of satisfaction. The overwhelming majority of users found the app easy to learn and use. The ease of reading and finding information were 68 – 72%, respectively.

Conclusion: Because self-management is vital for people taking Coumadin, using a game app as a supplement to traditional teaching could have significant positive impact on their health. As apps are increasingly easy to develop and smartphone use increases, apps should be developed to help people manage chronic diseases. Findings from this study support people's interest and ability to use apps.

Development and Usability Testing of a Mobile Health Game Application for Older Adults on Warfarin

by
Ernest Opoku-Agyemang

Dissertation submitted to the Faculty of the Graduate School of the
University of Maryland, Baltimore in partial fulfillment
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Dedication

First and foremost, I dedicate my doctoral dissertation work to my loving family in the United States who have endured and lived through the experiences of working and going to school. They stuck with me through thick and thin. Their support, patience, tolerance, and the many sacrifices that made it possible for me to complete this work will forever be a patch of green in my garden of memories. A special feeling of gratitude goes to my family in Ghana, who did not have much of education themselves but knew the difference between consumption and investment and chose to invest in my education. I also dedicate this work to my many friends in the United States, the United Kingdom, and Ghana who have been my best cheer leaders and inspired me to embark on this journey. I will always appreciate all they have done.

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List of Abbreviations

AHRQ	agency for healthcare research and quality
App	application
API	application programing interface
ATC	anticoagulation clinic
CDC	centers for disease control and prevention
CDSM	chronic disease self-management
CMS	centers for medicare and medicaid services
CLTUS	computer literacy and technology use survey
DVT	deep vein thrombosis
FDA	food and drug administration
HER	electronic health record
GDD	game design document
HIT	health information technology
HIPAA	health Insurance Portability and Accountability Act
IT	information technology
ITU	intention to use
ISO	international Standard Organization
IQR	interquartile range
IRB	institutional Review Board
PE	pulmonary embolism
PEOU	perceived ease of use
PHWUQ	perceived Health Web Site Usability Questionnaire

PT/INR	prothrombin Time and International Normalized Ratio
PU	perceived use
QOL	quality of life
QUIS	questionnaire for User Interface Satisfaction
RAD	rapid application development
RCT	randomized controlled trial
SM	self-management
Std. Dev	standard Deviation
TAM	technology acceptance model
UMB	university of Maryland, Baltimore
UMMC	university of Maryland Medical Center
UMSON	university of Maryland School of Nursing
UK/CSM	united Kingdom's Committee on Safety of Medicines
USDA	united States Department of Agriculture

Chapter 1. Introduction

1.0. Overview

As the number of people with chronic conditions continues to increase in the U.S., older adults who suffer from chronic and long-term conditions face greater challenges due to constraints in the healthcare system. Self-management (SM) has become a promising concept to overcome some of these challenges. However, the complexity involved in the management of some chronic conditions has prompted the search for complementary strategies. Mobile technologies can help individuals manage their conditions and promote healthy behaviors.

Self-management is particularly challenging for people on Warfarin (brand names: Coumadin, Jantoven) therapy because blood clotting must be monitored, foods that influence clotting must be regulated, and precautions must be taken to prevent bleeding. Although the usage of Warfarin has reduced in recent years due to the growing use of new oral anticoagulants, Warfarin still remains the most commonly prescribed oral anticoagulant in the United States (Dasgupta & Krasowski, 2020).This study developed and tested the usability of a mobile health game application (app) to educate patients about Warfarin therapy. For the purposes of this dissertation, the brand name *Coumadin* will be used interchangeably with Warfarin, especially in reference to the game app.

Chapter one introduces the challenges of educating patients with chronic diseases in regards to self-management and how game apps will help. The emergence of mobile health technology as a tool to improve health outcomes is explores. The concept of usability testing is presented before the chapter transitions to the purpose and research questions of the dissertation. The chapter ends with a brief overview of the Technology Acceptance Model (TAM) guiding the study. Chapter 2 reviews the literature related to older adults' use of information technology, particularly related to SM. The rise in mobile technology and the use of gamification to influence health outcomes are discussed. The TAM is explained in greater detail, including the demographic characteristics of adults in relation to the usability of health applications (apps) designed for that population. Chapter 3 presents the methods used for the study starting with the application development process followed by how the game is played. Heuristics evaluation and usability testing strategies are then presented. The last section of the chapter describes the sample and recruitment, data collection methods and statistical analysis used in the study before ending with a brief description of the human subject protection of the study.

Chapter four presents the findings and analysis of the study. The sample characteristics is described followed by analysis of how these characteristics affected the participants' Warfarin knowledge. Similarly, a correlational analysis between the user characteristics and usability of the app is discussed. The final chapter five discusses the results of the study. The discussions focus on the lessons learned from the app development and usability testing, as well as observations from the Anticoagulation Clinic (ATC) testing environment. The strengths and weaknesses of the study are then discussed before concluding with implications of the study for practice and recommendations for future research.

1.1. Background/problem

As the number of people with chronic multi-morbidities continue to rise, disease management presents a special challenge to the US. Health care system. The Centers for Disease Control and Prevention (CDC, 2016) estimate that about 25% of Americans have more than one chronic condition, and among older adults 65 years and older, the number is 75% (CDC, 2017). Chronic diseases are common and costly of all health problems. Seven of the top 10 causes of death in 2017 were chronic diseases. Of the $2.7 trillion annual health care costs, 86% is spent on people with chronic and mental health conditions (CDC, 2017; CDC, 2016).

The treatment adherence and management of chronic illnesses is often inadequate and causes a large financial burden to the US health system. The deficiencies in the health care system are particularly troubling for people with chronic conditions since, on average, they rely more heavily on the health care system, use the system more frequently, consume more health care resources, and are more likely to see multiple providers and develop long-term relationship with them (Davis et al., 2014).Interventions aimed at managing chronic diseases are usually associated with lifestyle changes, so patients need to be willing and able to constantly manage their own health conditions (Hale et al., 2015).

The appropriate strategy to manage chronic diseases, where lifestyle changes are critical for successful outcome, is self-management. About 70-80% of the long-term care population use self-management. Therefore, a small change in the management of self-caring patients could have a significant impact on the demand and cost of healthcare services (Wilson & Mayor, 2005; Coleman, 2010). The traditional methods of delivering chronic disease self-management (CDSM) by health professionals to their patients have been in one-on-one or group settings. For this conventional approach to be effective, however, it has to be patient-centered, continued over long periods, with short follow-ups, and regular reinforcement (Hale et al., 2015). Thus, these interventions are expensive to implement and difficult to maintain in primary care settings (Hale et al., 2015). Moreover, teaching self-management skills to patients these ways is particularly challenging for several reasons: not enough patient and provider communication time, healthcare providers may rely on written instructions that often are lost or thrown away, and patients and family members may be nervous and overwhelmed with discharge procedures and not focused on the teaching material. In addition, there are reimbursement constraints on primary care visits, which limits the amount of time that is spent with patients, even when there are multiple chronic conditions.

Innovative and less intensive interventions are needed. Mobile technologies may provide the needed help as they offer affordable and practical solutions. Additionally, mobile technologies promote increased patient participation, which is an integral component of CDSM (Hale et al., 2015).The development and adoption of smart mobile devices continue to increase, and the market for them is on the rise. According to the Pew Research Center (2019), 96% of Americans own a cell phone and the ownership of smartphones has grown from 35% in 2011 to 81% in 2019. The number of mobile app downloads worldwide increased from 140 billion in 2016 to 204 billion in 2019 (Clemens, 2020).

Mobile health applications (mHealth apps) have the potential to support CDSM, especially, the high-need, high-cost populations in managing their health (Singh et al., 2016). A study by Rowland et al. (2020) found that 56% of U.S. physicians have discussed mHealth with patients and 26% have been asked about mHealth by a patient. Research studies have reported that the emergence of mobile health technology has shown promise and serve as an effective conduit to deliver and manage interventions aimed at chronic conditions. These mobile platforms for the delivery of self-management interventions are adaptable, of low cost, and easily accessible (Bene et al., 2019; Whitehead &Seaton, 2016).

An increasing variety of apps are in the marketplace but only a few apps address the specific needs of patient populations who could benefit the most. Given that older adults constitute a large percentage of the population living with chronic conditions, apps could help them in self-management. The populations most commonly targeted by SM tools include patients with obesity, hypertension, physical handicaps, diabetes, cancer, older age, and dementia (Singh et al., 2016). Examples of these apps include: 1) WellDoc BlueStar®, a diabetes app that helps patients better understand their diabetes and provides tools for self-management; 2) Smart Blood Pressure® (Smart BP for short), an app that allows patients to record, track and analyze trends in blood pressure measurements; 3) ELEVATE Brain Training App®, designed to help patients improve cognitive function through educational games; and 4) NHS 24 MSK App®, developed by the National Health Service in the U.K. for patients with common musculoskeletal conditions.(MacMillan, 2020; iMedicalApps, n.d; FlintRehab, 2020).

One particular group of people who could benefit from such increases in self-management are those requiring long-term oral anticoagulation treatment, particularly those that are treated with Warfarin. Despite the recognized benefits from Warfarin therapy, it does require laboratory testing to assess therapeutic ranges. Older adults report dissatisfaction and reduced quality of life (QOL) resulting from the treatment, leading to poor adherence and decreased treatment efficacy (Lee et al., 2014). Warfarin is a high-risk drug and its management is very complex. Warfarin has a narrow therapeutic range to achieve desired anticoagulation without excess risk of bleeding (Zahid et al., 2020; Shuaib et al., 2014; Johnson, 2012). The medication is thus classified as a high-alert medication by the Food and Drug Administration (FDA), and considered among the top 10 medications with the largest number of reported serious adverse events (FDA, 2016). Therefore, patients on Warfarin must be monitored closely due to the high risk of bleeding. Poor management of Warfarin therapy puts patients at increased risk of thrombotic and hemorrhagic complications (Bereznicki et al., 2013; Johnson, 2012; Marcartto et al., 2018). While clinics have developed strategies and education materials to address anticoagulation management, people taking Warfarin could improve their self-care with additional support and reinforcement. A game app that helps people on Warfarin self-manage their care is one approach that has been found to be effective (King et al., 2013; Lister et al., 2014).

1.2. Patient safety through self-management of Warfarin

Patient safety is a particular concern when taking Warfarin and is part of self-management of anticoagulation therapy (Nagler et al., 2014). Several studies, including clinical trials and meta-analyses have concluded that patient safety can be improved through self-management of anticoagulation therapy (Garcia-Alamino et al., 2010; Heneghan et al., 2012; Bloomfield et al., 2011). These studies have documented better anticoagulation control, less thromboembolic complications, increased quality of life, and, in part, a reduced mortality in the self-management group when compared with the usual care group.

The challenges of patient self-management with regard to Warfarin, such as ensuring safety, lifestyle limitations, and other potential side effects, have prompted the search for complementary strategies, such as mobile technology to facilitate patient self-management. Furthermore, an approach that combines the elements of games and the power of technology, gamification, may make the process more enjoyable. This concept will be explored further in chapter two.

Games are conceptualized as motivational play for older adults and can influence social skills, self-perception, empathy, psycho- social functioning (e.g., self-confidence and achievement motivation), and cognitive skills (e.g., attention, planning, and creativity) (Brown-Johnson, Berrean, and Cataldo, 2015). The older adult's use of mobile technology is partly based on the notion that it can potentially empower them in self-management and can simplify the complex care systems that many older adults with chronic conditions face (Lee et al., 2014).

1.3. Purpose of the study

The overall purpose of this study was to develop and evaluate the feasibility of a game app for self-management of Warfarin for older adults by applying evidence-based usability principles to enhance the user experience. The study has two specific aims: 1) To design and develop a mobile game app to educate patients on Warfarin self-management; and2) To conduct usability testing of the new game by patients on anticoagulation therapy.

Three questions were examined:

1. What is the usability of the Warfarin game app based on the heuristics evaluation by experts?
2. What is the perceived usability of the Warfarin game app and does it vary by the end user's demographic characteristics?
3. What is the satisfaction, ease of use, and usefulness of the Warfarin game app?

1.4. Theoretical framework

This study was guided by the Technology Acceptance Model (TAM). For the app to be effective, the older adult patients must accept the game and use it. Therefore, in order to forecast technology usage behavior, it is important to understand the factors that influence the usage and acceptance of technology (Chen and Chan, 2011). The TAM can help explain the user's acceptance or rejection of the systems (Davis, 1986, 1989). The relevant constructs of the TAM model shown in Figure 1 will be discussed in detail in chapter two under the review of literature.

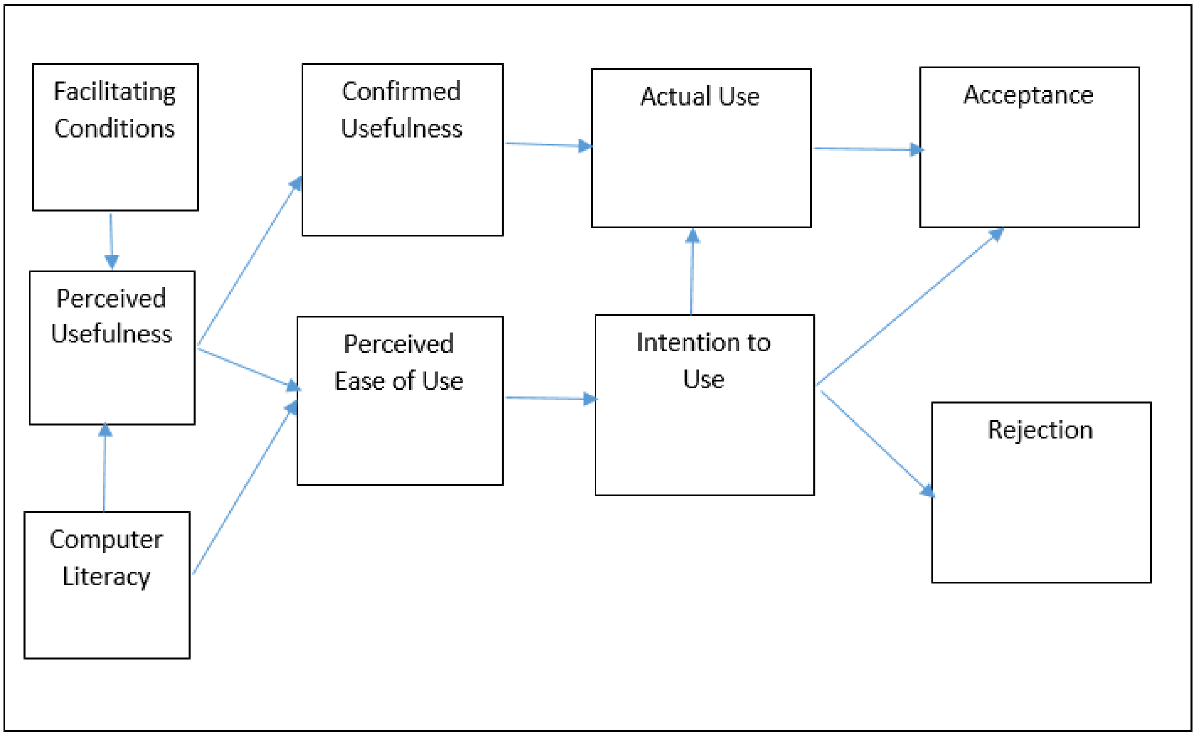


Figure 1: Conceptual model of information technology (IT) system use: Adopted from TAM model by Davis, 1986.

Chapter 2. Review of the Literature

2.0. Overview

This chapter introduces the growing challenges of chronic disease and self-management. The proliferation of mobile health technology as an alternative strategy to manage chronic diseases through self-management is discussed, particularly the safety concerns that may relate to it. The review also presents specific cases where mobile apps have been used to influence health outcomes. The use of games as a strategy is emphasized while acknowledging the challenges associated with the older adults' technology use behavior. Usability concepts in relation to this population is explored before a detailed review of the technology acceptance model (TAM) by Davis (1989) is presented. Within the TAM, PU and PEOU were discussed as the major factors when using information systems. The review focused on specific applications of the TAM as they related to older adults. The chapter ends with a discussion summary of what have been reported in the literature on the topic area.

2.1. Chronic disease and patient self-management

Chronic illness care is a predominant challenge facing the US health care system, which has led to the development of care management methods including the chronic care model to cater for this patient population (Nagler et al., 2014; Gerteis et al., 2014). At the core of the chronic care model is self-care or self-management where the patients themselves become the principal caregivers and are expected to self-manage increasingly complex care. People live with chronic illness for many years so the chronic care model stresses that the management of these illnesses should be taught to most patients since substantial segments of that management – diet, exercise, self-measurement (e.g., using patient meters) and medication use – are under the direct control of the patient (Baptisa et al., 2016). Patient self-management has the potential to make the greatest difference to chronic condition management since patient self-management covers 70-80% of the long-term condition population. Consequently, minor changes in the management of patients' self-care could have a major effect on the demand and cost of healthcare services (Coleman, 2010).

The problem is that teaching self-management skills to patients is particularly challenging, especially for older adults. The challenges are due to numerous reasons: not enough patient and provider communication time, healthcare providers may rely on written instructions that often are lost or thrown away, and patients and family members may be nervous and overwhelmed with discharge procedures and not focused on the teaching material. With regards to the older adults, it is difficult for care providers to design education programs that allow for incremental knowledge gain, practical and/or remote learning.

Moreover, the complexities involved in teaching self-management skills vary according to the type of chronic condition and the patient population involved. Performing self-management is particularly difficult and demands a substantial effort from older adults (Huygens et al., 2016).

2.1.1. Warfarin therapy and self-management

One particular group of people who could benefit from education in self-management are those requiring long-term oral anticoagulation treatment that are treated with Warfarin. Although new oral anticoagulants, such as Xarelto® and dabigatran have been recently introduced and approved by the Food and Drug Administration (FDA), Warfarin is still the most widely used oral anticoagulant for patients with thromboembolic risk (Baillargeon et al., 2013; Bereznicki et al., 2013; Teklay et al., 2014).

Even though older adults on Warfarin benefit from the therapy, studies have shown a certain level of dissatisfaction and reduced quality of life (QOL) due to the treatment. The net effect is poor adherence and reduced efficacy of the treatment (Lee et al., 2014). Because Warfarin has a narrow therapeutic range and considered a high-risk medication patients taking the drug must be monitored closely due to the high risk of bleeding (FDA, 2016; Zahid et al., 2020; Solvik et al., 2019). Poor management of Warfarin therapy puts patients at increased risk of thrombotic and hemorrhagic complications (Bereznicki et al., 2013). While clinics have developed to address anticoagulation management, people taking Warfarin could improve their self-care with additional support and reinforcement. An app that helps people self-manage their care is one approach. Studies have shown that using such apps have proved to be effective (Bene et al., 2019; Whitehead & Seaton, 2016).

Although Warfarin therapy has been used for over 60 years (Miyamoto et al., 2015), its management still remains a challenge. Among outpatients, the requirement for frequent monitoring, dose adjustments, and regular contacts with the provider can render Warfarin self-management labor intensive and complex. Warfarin self-management is particularly challenging especially for older adults since it often involves changing doses, frequent testing, regulation of foods that may interfere with the drug, and safety precautions to prevent bleeding(Zahid et al., 2020; Dharmarajan & Dharmarajan, 2008). Providers generally educate patients verbally and/or with written materials that usually are passive and not sufficient to provide the needed education. In clinical practice, patients typically receive intense education in one session. Also, it's not common to check how much information a patient retained during education. Paper instructions and reminders may be appropriate for some patients and situations but learning how to manage specific aspects of self-care, such as diet and medications, necessitates that a patient apply what they have learned to their own situation. These aspects of self-care raise the question whether patient safety can be ensured through self-management.

2.1.2. Effectiveness of Warfarin Self-Management

Patient safety is a particular concern when taking Warfarin as part of self-management of anticoagulation therapy (Nagler et al., 2014). Several studies, including clinical trials and meta-analyses (Garcia-Alamino et al., 2010; Heneghan et al., 2012; Bloomfield et al., 2011) have concluded that patient safety can be improved through self-management of anticoagulation therapy. These studies have documented better anticoagulation control, less thromboembolic complications, increased quality of life, and, in part, a reduced mortality when compared with usual care. In older adult patients, self-management of oral anticoagulation was reported to be better for the prevention of major thromboembolic and bleeding complications, and for the quality of oral anticoagulation control compared to routine care (Solvik et al., 2019; Siebenhofer et al., 2008; Soliman et al., 2009).

Despite the evidence of improved safety and other outcomes, Nagleret al. (2014) argue that not all older adults on anticoagulation therapy are suitable for all self-management strategies. The authors identified four requirements that patients qualifying for anticoagulant self-monitoring should fulfill: 1) long-term treatment, 2) no vision impairment that precludes appropriate testing, 3) have the cognitive ability to receive training, and 4) be willing to take an active role in their illness. Although these requirements appear to exclude some members of the target population that are prescribed Warfarin, those factors should be considered on case-by-case basis depending on how they impact the patient's ability to use the technology, navigate the smartphone? Or maybe device screens, and play the game.

2.1.3. Technology approaches to self-management

The challenges of patient self-management with regard to Warfarin, such as ensuring safety, lifestyle limitations, and other potential side effects, have prompted the search for alternative strategies, such as mobile technology to facilitate patient self-management to improve attitudes toward Warfarin therapy and reduce perceived barriers. These innovative approaches will be beneficial, especially to older adults who have shown increasing use of mobile technology. The justification for older adults' use of mobile technology is not unreasonable. Although older adults in the US are considered late adopters of mobile technology compared to their younger counterparts, recent trends point to a gradual movement by the elderly population towards the use of smartphones and mobile devices (Pew Internet Research, 2019a). In 2016, 74% of American adults between 50 to 60 years own a smartphone and 42% of 65 years and older own a smart phone (Pew Internet Research, 2019b). The vast majority of older adults (85%) are willing to use mobile devices and many of them believe it will help monitor for adverse health events. Several authors have also written about the older adult's use of specific mobile technologies, such as games (Parker, Jessel, Richardson and Reid, 2013).

According to Lee et al. (2014), the older adult's use of game technology is partly based on the notion that it can potentially empower them in self-management and can simplify the complex care systems that many older adults with chronic conditions face. Mobile technology use by older adults is considered a resource for coping with daily living (Lee et al., 2014). Learning new apps and technology skills helps lessen isolation, keep the brain active, and allow older adults to monitor their own health (Schlomann et al., 2020).

2.2. Designing an app for older adults

In order to encourage the older adult population to use a game app, the design has to suit their needs based on demographic characteristics and medical history. A research study (García-Peñalvo et al., 2014) listed usability factors to consider when developing apps for senior citizens.

Based on these recommendations, and given the target population of this study, those design principles will be considered. In general, some of the features to include in mobile apps designed for older people are: font size between 36pt – 48pt, one-level navigation, and buttons arranged at the bottom of the interface so the input-hand will not hide the screen (García-Peñalvo et al., 2014).The game will be designed to:

- Use minimalist design to prevent cognitive overload in our target population.
- Provide large icons that are easy to interpret for function and interaction logic.
- Avoid the use of irrelevant information on the screen.

- Since color discrimination ability declines with age, the design will maximize contrast and avoid use of excessively bright colors.
- Clear instructions on how to use the app (game will be mostly text based) will be provided, including help screens which should be prominently displayed.
- Use a simple navigation structure (such as back, forward buttons, or Menu buttons).
- Provide only those features in the app that the elderly user will need to accomplish the task.
- Provide feedback when an action is taken. This may include a subtle animation or sound when a button on screen is pressed, or a color change on a menu item when it is selected. This feature could be augmented by the use of a virtual character (game assistant).
- Limit the use of multi-touch gestures (swipes) within the app.
- Provide a sense of accomplishment when a game scenario is completed. This promotes self-efficacy.

2.2.1. Older adults use of technology

A Pew Research Center estimates that about 75% of people 65 years and older go online, 51% own tablets, and a large number of them own smartphones although many seniors remain detached from digital life (Anderson & Perrin., 2017). The report also indicates that older adults face unique barriers to adoption, ranging from physical challenges to a lack of comfort and familiarity. One of the main challenges with respect to technology use among older adults is the lack of confidence in their ability to learn and use electronic devices. In spite of these challenges, about 58% of seniors believe technology has had positive impact on their lives, and in some health conditions (Anderson & Perrin., 2017).

2.3. Mobile health apps

The number of mobile health apps is increasing rapidly in recent years and has gained attention because evidence is starting to show that their use can lead to healthier behavior and better health (King et al., 2013; Hawn, 2009). In 2015, the number of mobile health apps available on the iTunes (iOS) and Google Play (Android) app stores is estimated to be over 165,000 in the United States alone (IMSHealth, 2015, p.1). As Dicianno et al. (2015) noted, the growing popularity of mobile health apps is fueling and promoting further development and use in practice**.** By 2018, the FDA and the Mobile Health Market Report by Research 2 Guidance have estimated that 3.4 billion smartphone and tablet users will use mobile health applications (FDA, 2015, para. 2; Miller, Cafazzo & Seto, 2014). Mobile applications are now beginning to serve an important role in facilitating self-care. A growing feature of mobile health applications that are being leveraged to improve self-management behaviors is gamification or health games (Miller et al., 2014; Edwards et al., 2016).

One of the main selling points of health apps including health games is their ability to improve outcomes through self-management of patients with chronic diseases (iMedicalApps, 2017). While many studies have supported the notion of using mobile technology such as health games to improve outcomes (AlMarshedi et al., 2016; Clochesy et al., 2015), others have concluded that the scientific evidence to support the effectiveness of these technologies is not clear (Lister et al., 2014; Connolly et al., 2012).

Therefore, more research studies are needed to investigate the use of health games, for example, to improve outcomes through self-management. However, as AlMashedi et al. (2016) reported, some mobile health care interventions in their current form lack effective and engaging qualities, and therefore, may not appeal to many patients and their effects are temporary. Health games have now appeared as a novel approach to influence health behavior and improve outcomes through self-management.

2.3.1. Growth in mobile health apps to improve outcomes

The number of mobile health apps is increasing rapidly in recent years and they have gained attention because evidence is starting to show that their use can lead to healthier behavior and better health (King et al., 2013; Hawn, 2009). In 2015, the number of mobile health apps available on the iTunes (iOS) and Google Play (Android) app stores is estimated to be over 165,000 in the United States alone (IMSHealth, 2015, p.1). As Dicianno et al. (2015) noted, the growing popularity of mobile health apps is fueling and promoting further development and use in practice. By 2018, the FDA has estimated that 3.4 billion smartphone and tablet users will use mobile health applications (FDA, 2015, para. 2). Mobile applications are being adopted almost as quickly as they can be developed because research studies are beginning to show that health games can help patients with chronic diseases to promote wellness and healthy lifestyles (Chalier et al., 2016; Hawn, 2009). One group that stands to benefit from the growth in mobile health technology is the older adult population that has shown increased usage of technology solutions in their everyday lives.

2.4. Gamification in health apps

Gamification is a general term used to describe the process of using the elements of games to motivate and engage people to advance goals outside what is traditionally regarded as games. Gamification in health is now being used in healthcare (Koivisto & Hamari, 2014) and has appeared as a popular strategy and as a means of influencing health behaviors (King et al., 2013; Lister et al., 2014). The term “serious games” or “health games” has emerged and being used to describe the use of mobile app technology, especially those with educational intent, in healthcare (Ulicsak, 2010, p.2; Miller et al., 2016; Lau et al., 2014; Charlier et al., 2015).

Health games have many advantages in helping patients in disease management. According to the Robert Wood Johnson Foundation (RWJF), game-based approaches challenge, motivate, and engage users in a way that no other medium can (RWJF, 2004). Using games allow the rehearsal and reinforcement of self-care skills until patients achieve set goals. Mobile games can be played anytime, anywhere, and even without Internet access. Unlike printed information, which is often conveyed passively via a single education session, games offer patients multiple opportunities to learn problem-solving skills and deeper engagement in their own health management. Individuals seldom play a game only once, and repeated playing may enhance understanding of the information shared by the game.

In addition to the design issues discussed earlier, studies have shown that seniors may encounter challenges in adapting and accepting new technologies (Abidin, & Firdaus, 2016). The older adult population may become disengaged and exclude them from the benefits of technology to manage their health. The disengagement of this population presents a number of challenges to the app software design community (Coleman et al., 2010). In order to ensure that health applications are suitable for older adults to have a better experience, it will be helpful for health apps designers to engage in adequate usability testing taking into consideration the characteristics of the older adults. Therefore, this dissertation will focus on usability testing of a proposed gaming application for older adults.

2.4.1. Effects of mobile apps on health outcomes

In a scoping review to assess the quality, bias, and outcomes of mobile apps in the available literature, Singh et al. (2016) found that 32% (56 out of 175) studies validated mobile apps ability to measure outcomes while 85% (74 out of 87) found users to be generally satisfied with the use of the their app. There are specific studies that have targeted mobile apps ability to improve outcomes in areas such as, nutrition, wellness, mental health, and perioperative care. For example, a systematic review to assess the effectiveness of mobile phone and tablet apps in self-management of key symptoms of long-term conditions showed the potential of apps to improve symptom management through self-management interventions. The study concluded that the use of mobile health apps has the potential to improve health outcomes of patients with chronic diseases by enhancing symptom control (Whitehead & Seaton, 2016).

In another systematic review, DiFilippo, Huang, Andrade and Chapman-Novakofski (2015) reported an increase in adherence to diet monitoring and decreased effort to continue diet without the app. Moreover, the results of a randomized controlled trial (RCT) of healthy lifestyle indicators demonstrated the positive impact of using web-based app interventions (Safran Naimark et al., 2015). In a similar RCT study, Clarke et al. (2013) reported rapid improvements in work and social functioning with participants who had middle to moderate depression, anxiety and/or stress. Additionally, in perioperative care, an app was used effectively in patients undergoing routine cardiac procedures to ensure 100% compliance with instructions along with excellent patient satisfaction scores (Morsli & Mathew, 2015).

Arnhold et al. (2014) conducted a systematic review to examine whether available mobile apps for diabetics serve the special needs of diabetes patients 50 years and older. The authors concluded that the usability of the diabetic apps was moderate to good. Another observation from this study was that, the apps that offered small range of functions performed better than the multifunctional apps. To investigate the overall effectiveness of digital health games on healthy lifestyle promotion outcomes in a meta-analysis study, DeSmet et al., (2014) found that serious games have small positive effects on healthy lifestyles. As some of these studies have shown, usability plays an important role in the success and effectiveness of the mobile health apps.

2.5 Usability testing of mobile game apps

For the health game-based approach to work and be effective, the app must be usable. According to Nielsen (1993), if a program is difficult to use and has many errors, people will not to use it. Russ et al. (2010, p.702) stated that "usability testing can help generate ideas that will enhance the quality and safety of health information technology". Therefore, there is the need for usability testing before product implementation. Usability testing refers to evaluating a product or service by testing it with representative users. The goal of usability testing is to identify any usability problems, collect qualitative and quantitative data and determine the participant's satisfaction with the product (HIMMS, 2009). The International Standard Organization (ISO) defines usability as the "extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use" (ISO, 1998, 9241-11). Nielsen (1993) defined the five components of usability as: 1)learnability (how easy it is for first time users to learn the system to complete basic tasks), 2) efficiency (how quickly users can perform tasks once they have learned the system), 3) memorability (how users can easily re-perform the tasks after a period of not using the system), 4) errors (how many errors do users make, how severe are the errors, how easily users can recover from the errors), and 5) satisfaction (how much users like the system).

There are several methods for usability evaluation found in the literature (Moore et al., 2009; Nielsen, 1993; Stinson et al., 2010). Among various techniques, the most frequently used methods are: (1) heuristic evaluation, (2) user testing, and (3) surveys, or focus groups. Heuristic evaluation, one of the usability evaluation methods, is a professional review of the website using commonly accepted rules of good judgment by experts (Nielsen, 1993). It is time- and cost-effective compared to user testing with end users (Nielsen, 1993). Another frequently used method is user testing. User testing is the technique that asks people who are representative of the target audience to evaluate the website (Rubin & Chisnell, 2008). Usability evaluation with real users is the most fundamental and irreplaceable method because it provides direct information about exact problems (Nielsen, 1993).

To get the most valuable evaluation of a new system or technology from participants, a think-aloud method (continuously verbalizing thoughts) is frequently used

(Nielsen, 1993). This method may help researchers to understand how users view health educational programs and what frustrates or discourages them. However, the main disadvantage of the method is that it seems unnatural to most people (Nielsen, 1993). Nielsen (1993) recommended giving a short think-aloud demonstration to participants before the testing to minimize this drawback. Both heuristic evaluation with experts and user testing with end users can help the researchers find more usability issues. Heuristic evaluation may find issues that are not identified by user testing, and user testing may also uncover issues that are not caught by heuristic evaluation. Therefore, employing both evaluation methods is recommended for the best result as the two methods supplement each other (Nielsen, 1995).

A user survey is an effective method to assess users' perceived usability. Questionnaires and interviews are the main tools usually used in user surveys but we will focus on survey questionnaires in this examination. Questionnaires are probably the most frequently used method of summative evaluation of user interfaces. Questionnaires involve asking users a set of questions and recording their answers. Questionnaires may be printed on paper or presented in an electronic format on a computer and administered interactively by the users via the Internet (online) without anyone present (Nielsen, 1993). Online surveys often target populations expected to have regular access to the internet, such as students or university staff (De Bernardo & Curtis, 2013). Nielsen recommends at least 30 users for software usability testing.

Several survey questionnaire tools are available such as the Questionnaire for User Interface Satisfaction (QUIS) which is used to measure user satisfaction with the software/app (Chien et al., 1988). Another example is the Software Usability

Measurement Inventory (SUMI) which has a checklist of 50 statements and asks the users to check a box to indicate their agreement, disagreement or remain undecided regarding their view on software quality (Coleman, 1993). The Perceived Health Web Site Usability Questionnaire (PHWSUQ) questionnaire, a 12-item tool was developed by Nahm, Resnick, and Mills (2006) for use by older adults. The PHWSUQ is the tool that will be used for the proposed study at the end of the user testing.

The use of mobile technology is pervasive by both the younger and older generations who are using mobile devices, such as the smart phone or tablet. Mobile devices are promising tools to improve the quality of life for the elderly (Plaza et al., 2011). Some studies have shown the use of mobile apps resulted in improved health outcomes (Singh et al., 2016). The use of health apps technology, such as the game apps by the older adults deserves additional considerations due to their unique demographic characteristics. A proposed solution is an app, which takes into account the usability considerations of the older adult population. The question remains whether the older adults will be willing to accept and use a proposed technology.

2.6 The Technology Acceptance Model

This study adopts the Technology Acceptance (TAM) model by Davis (1989) to explore the factors that determines the older adults' acceptance of a Warfarin game app. Davis (1989) stated that a major determinant of whether a user will actually accept or reject a system is determined by the user's intention to use the system. There are two relevant external variables of behavioral intentions: perceived usefulness (PU) and perceived ease of use (PEOU). A systems usage is ultimately determined by the user's intention to use it. PU is defined as the perspective user's subjective probability that using a specific application system will increase his/her job performance and PEOU which refers to the degree to which the prospective user expects the target system to be free of effort (Davis, 1989). TAM has evolved over the years and the determinants of PU and PEOU has gone through changes in TAM2 and TAM3 (Venkatesh & Bola, 2008). Constructs, such as voluntariness, subjective norm, image, and job relevance were added in these latest versions.

The various determinants may help to predict acceptance of the program. However, since the focus of this study is usability of a health game app, some determinants are deemed irrelevant and not suitable for the purpose of this study. As a result, only the two core constructs of TAM (PU, PEOU) will be included in this study. ITU will not be measured since there will be no actual use of the app by the patients. In accordance with this theory, after the development of the game app, we will test usability of the app by employing heuristic evaluation and user testing as well as using the PHWSUQ (Nahm et al., 2006). These constructs will inform this study since they are common to all the TAM versions either directly or indirectly. These constructs will be explored further to the extent that they influence technology usage behavior.

To predict technology usage behavior in any meaningful way, it is important to explore and understand the factors that influence usage and acceptance of technology (Mitzner et al., 2010; Chen and Chan, 2011). Using the TAM as a model is effective when applied to older adults, where the basic constructs, such as PU and PEOU, are critical for their continuing usage. To understand how older adults interact successfully with technology devices and systems, it is essential to take into account the biophysical and psychological characteristics, as well as abilities and problems older adults experience (Chen & Chan, 2011). Sustar et al. (2008) examined the importance of health information technology (HIT) systems design for older adults and found that that older adults are a large market group with various needs and preferences, so HIT systems designers and developers must consider those factors when creating these systems. Shneiderman and Plaisant (2010) reinforced this view by stating that, understanding the human factors of aging can help designers create user interfaces that facilitate access among older adult users. The older adults will not become users of technology unless systems designers and developers are able to change the older adults' views about the usefulness of technology or until technology itself changes to accommodate the older adults' interests and needs (Coleman et al., 2010). Systems that fail to consider the older adults special needs run the risk of being marginalized or abandoned (Zajicek & Brewster, 2004).

In making health HIT systems more usable, it is incumbent upon systems designers to involve the older adults in the process. Czaja and Lee (2007) wrote that it is a necessity to involve the older adults in the design and testing of application systems built for the use of this population. The involvement of the older adults will help systems designers and developers to learn from them what functionalities and attributes are important to them, what motivates them about the use of the app, and what factors impede the usability of the app they are using. By so doing, designers will be able to refine and improved technology systems that could improve the lives of the older adult population. Over the years, studies have been conducted about the application of PU and

PEOU that are the two main concepts of the TAM model that explain the user's intention to use and actual use of a HIT systems.

2.6.1. The TAM model and older adults

Davis (1989) suggested that the TAM is able to explain and predict users' intention to use a HIT system. The TAM provides insight that can be used to maximize the adoption of HIT by end users, such as the patient (Tubaishat, 2017). A review of the literature showed that limited studies exist that have used the TAM to explore older adults' perception of usefulness and ease of use of mobile apps and games specifically. Some studies used the TAM as a guiding theoretical framework, while others tested and validated the TAM. This study uses the TAM as a theoretical foundation since the validation of the model is beyond this dissertation project.

The review found considerable variations reported in the literature. While some studies focused on web applications, others explored non-specific applications. For example, Hong et al. (2014) tested the usability and acceptability of a web application to promote physical activity among older adults. Testing usability and acceptability is an important step in developing age-appropriate and user-friendly apps, especially for older adults. Testing usability and acceptability can help reveal user's experiences and feedback in a real life setting (Hong et al., 2014). In another study, usability testing was done on a website by patients in focus groups. Website modifications were made following the patient testing. This study highlighted the fact that user involvement in web design can ensure that patient needs are met (Connolly, et al., 2012). Yet other studies stressed the importance of PU and PEOU in the design and development of HIT systems.

Davis (1989) noted that PU and PEOU are important in determining both the intention to use and actual use. PU of system application is a reliable predictor for future usage. Davis showed that there is a significant correlation of PU with self-reported current usage and self-predicted future usage. In much the same way, a system's PEOU also proved to be a reliable indicator but unlike PU, PEOU strongly depends on actual implementation of systems functionality. Rocker (2009) conducted a multi-national study to evaluate the PU and PEOU of an intelligence system and found that although usefulness and ease-of-use ratings were high, there is still a great potential to increase the usefulness and ease-of-use of application systems in order to identify reasons for potential low ratings.

Involving users in the design and development stages ensure systems are relevant and user-friendly, which in turn results in greater chance of the users forming intentions to use and actually using the proposed technology (Davis et al., 1989). Or and Tao (2012) conducted a usability study of a computer-based self-management system for older adults with chronic diseases and reported that usability evaluation could be a quick and effective way to identify problems of HIT systems at the early stages. Usability evaluation is a crucial step in system development to ensure that system features match the users' true needs, expectations, and characteristics. Usability evaluation also minimizes the likelihood of the user's difficulties during system use that could lead investigators to draw mistaken conclusions about system effectiveness (Or & Tao (2012).

In a systematic review of designing telemedicine systems for geriatric patients, Narasimha et al. (2017) reported that there is limited valid and reproducible scientific research about usability evaluation at various stages of system development. System designers should therefore consider the age-related issues in cognition, perception, and behavior of geriatric patients while designing healthcare applications.

Thus far, the literature has shown that the importance of conducting adequate usability testing cannot be overemphasized. While usability studies targeting the older adults use of mobile health applications is limited, available evidence in the literature gives credence to the relevance of the key constructs of the TAM model as the theoretical basis for the development and usability testing of mobile health apps that have sprung up in the healthcare industry to help improve health outcomes.

2.7 Summary/discussion

The review focused on the use of technology systems to facilitate the SM of older adults with chronic diseases. Although there are several technology acceptance models, this review focused on Davis (1989) TAM model to predict acceptance of health information technology systems. Selected studies explored the two key constructs of the TAM model – PU and PEOU – and their specific applications regarding the acceptance or rejection by their intended users. The review of the literature revealed that limited studies exist that have used TAM to explore the older adults' perception of usefulness and ease of use of mobile apps systems.

Some of the studies reviewed were tailored for web application systems while others were focused applications that are not related to healthcare. Regardless of the application type, all the studies emphasized the importance of conducting usability testing at various stages of the application design and development to simulate the real user patterns. However, some of these studies lamented the lack of limited research that provides valid and reproducible scientific usability evaluations at different stages of technology systems development.

In addition to reviewing user acceptance of technology systems, the review also focused on the proliferation of mobile health apps and their effectiveness in improving health outcomes. A large number of the reviewed studies focused on the positive impact of the apps systems in improving outcomes. The evidence in the literature supports the education and behavioral outcomes. The most frequently occurring articles were focused on the effectiveness of the health apps in managing a limited group of disease conditions. Diabetes, obesity, physical activity, and healthy eating habits apps emerged as the primary focus of the studies reviewed. This implies saturation of these health apps and related studies in a very narrow focused areas or clinical domains. The review did not find specific studies evaluating apps designed to help adults on Warfarin therapy manage their disease condition.

Chapter 3. Methods

3.0. Overview

The methodology section was divided into two coinciding with the two main phases of the study: 1) the design and development of the Coumadin app; and 2) the usability testing of the app. The chapter starts with the app development including a description of the technology and platform, a summary of the game content, highlights of the features of the four games, and the heuristic evaluation conducted during development. The second part describes how the usability testing was conducted with Coumadin users. This includes the setting, sample, instruments, and procedures. The section concludes with a summary of the data analysis, study challenges, and human subject protections.

3.1. Design and development of Coumadin app

3.1.1. Development strategy

The strategy for software design and development involved the Kanban® agile approach and rapid application development (RAD) methodologies (Hoffer et al., 2019). An iterative and incremental development approach was applied. Using this approach, several versions of the game were developed and refined until a final prototype was achieved. One major advantage for using the Kanban® agile approach for the development cycle was allowing the development to be flexible and accommodate any reprioritization that may have occurred and making it easier to incorporate changes in the development process (Hofmann et al., 2018). In addition, the iterative and incremental model allowed the vendor (small team of software developers) and the dissertation committee members to work progressively on both the requirements document and the prototypes.

3.1.2. Platform and technology

Apple iPhones and iPads were selected as demonstration platforms for several reasons: 1) it is a fast, apps that run on the iOS platform are free, and well-supported development environment; 2) the same code can run on both iPhone and iPads with minimal changes; and 3) there is widespread use of these mobile devices in the target population. These inherent advantages of the Apple iOS platform made it the preferred software platform for this project. Modern open source technologies were used, and the programing languages were Angular.js, Hypertext Markup Language (html) and JavaScript. The app was hosted on secured Google's Firebase cloud mobile platform, which is Health Insurance Portability and Accountability Act (HIPAA) compliant.

A responsive app design technique was used to ensure the app is responsive to different screen sizes and resolutions to best meet the iPhone and iPad programming needs. The iOS platform requires small screen size and a smaller amount of content per screen. The responsive design techniques was utilized with the touch screen and other native functionalities of the modern smart phone and mobile devices. The responsive design enables the app to run on both devices without any noticeable differences except screen size. This saved development time and decreased errors in coding and in playing the game. Developing an app for iOS and Android would mean developing and maintaining source code for two disparate platforms, requiring different programming tools and different application programing interfaces (APIs) (Wattanasoontorn et al., 2013). Since this dissertation had limited resources for development and the purpose was for proof of concept, these requirements would be beyond the scope of the study (participants were not required to bring their own phones since the researcher provides iPhones for the testing). However, because of the responsive design techniques employed, the app can adjust to different screen sizes and resolutions and works on some Android platforms and desktop computers running the Windows operating system, with minor differences in the interface and screen resolution.

3.1.3. Game/app content and interface development

The game app development process began with the Game Design Document (GDD), which gives a broad overview of the game. The GDD contains general information about the game, story, and the mechanics of gameplay. The level of detailed design and technical specifications were contained in separate documents and were submitted to the vendor for development. The game was developed at the fifth grade literacy level to reflect possible low literacy for some older adults. Patient education materials (PEMs) about anticoagulation are written at an average readability level of 10^{th} grade whereas about 20% of the US population read at or below the fifth-grade level (Kim et al., 2005). The Joint Commission (2010) stated that PEMs should be written at or below a fifth grade reading level.

To ensure that the reading level of the proposed app conformed to the Joint Commission's recommendations, two online readability calculators recommended by the University of Minnesota Biomedical Libraries for the creation of PEMs were used (University of Minnesota, 2012). One of the calculators is the WebFx Readability Test Tool (WebFX, n.d) and the other is the Online-Utility Readability Calculator (Online-utility, n.d). These web-based tools are capable of analyzing the grade reading level of

English text using a number of readability indices. These indices are also based on recommendations from the Health Literacy Advisor, a software tool to assess and improve the readability of documents using plain language principles (Health Literacy Innovations, n.d). Some of these indices, such as the Online-Utility, are endorsed by the Centers for Medicare and Medicaid Services (CMS). The Online-Utility offers ideas on how to improve readability by specifying sentences that increase or decrease the grade reading level of the text of a particular content (Stossel et al., 2012). This project used the WebFx tool to assess the grade level of the app that was under development. Based on the WebFx Readability Test Tool, the reading level of the proposed app was rated at grade level 4 as follows:

"Your page (http://coumadin-hero.firebaseapp.com) has an average ***grade level of about 4****. It should be easily understood by 9 to 10 year olds."*

This was consistent with the researcher's goal of developing the app at or below the fifth grade level. The educational content developed by AHRQ (2010) and the UMMC/Anticoagulation Clinic (ATC) for Warfarin education requires minimal numeracy skills, such as simple addition and subtraction. The literacy level of the game content was designed to match the AHRQ and UMMS/ATC material. No numeracy skills were required to play the game.

3.1.4. Design of the Coumadin app

The name of the game is "*Coumadin Hero*", was chosen as a representation of showing courage and being a hero in caring for oneself. The following are the major highlights of Coumadin Hero as a game app.

1. App versus game. While the app is referred to as a game, it is not really a game in the literal sense but that due to the gamification aspects of the app, the word "game" was kept as part of the name. It is important to recognize that the app is designed to help people who are on Warfarin to self-manage their care. However, gaming elements are used to motivate and engage the users (i.e., gamification). The name change came about after a conversation with a friend who has no expert knowledge about health applications technology. The game concept is not abandoned since it is the method and a tool to change health behavior.
2. Overall organization. The app consists of a landing page which displays three mini games focusing on specific self-care topics for people taking Warfarin: diet, medication interactions, and blood clotting. Figure 3.1 (Design grid) and Figure 3.2 (Landing/home page) illustrates the overall game design, reflecting a consistent approach to each of the three games. The *Coumadin Hero* welcome screen is common to all the mini games. For each mini game, there is an information screen, an instruction screen, a game play screen, and a scoring screen. Figure 3.2 shows *Coumadin Hero* welcome screen and main storyboard. This dissertation research is focused on Vitamin K containing foods and their effects on Warfarin. Therefore, only the diet -Vitamin K food selection game will be discussed.
3. Mini-game screen organization. The content was presented as a combination of screens, short description text boxes, and occasional hints during game play. The text on a screen or button is intended as instruction(s) or information for the user/player. The actual specifications regarding font sizes, text color, buttons,

screen/background colors, and other characteristics were made in consultation with dissertation committee and the vendor. A top menu bar is common to all screens. Additional explanatory information is presented under a "More Info" button on the individual screens. The information provides patients with Warfarin Patient Education Material similar to what is given to patients who visit the ATC Clinic.

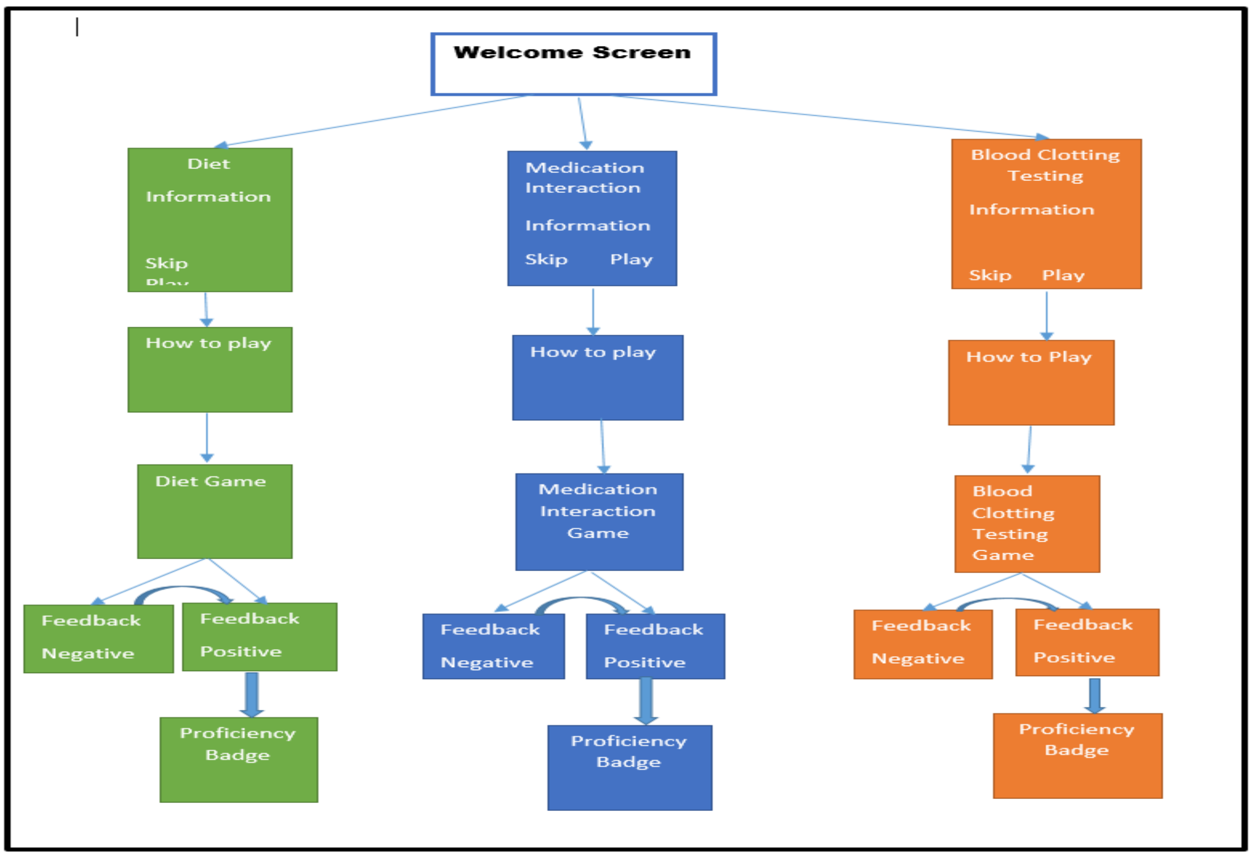


Figure 3.1: Coumadin Hero Game Design Grid (Navigation Diagram)

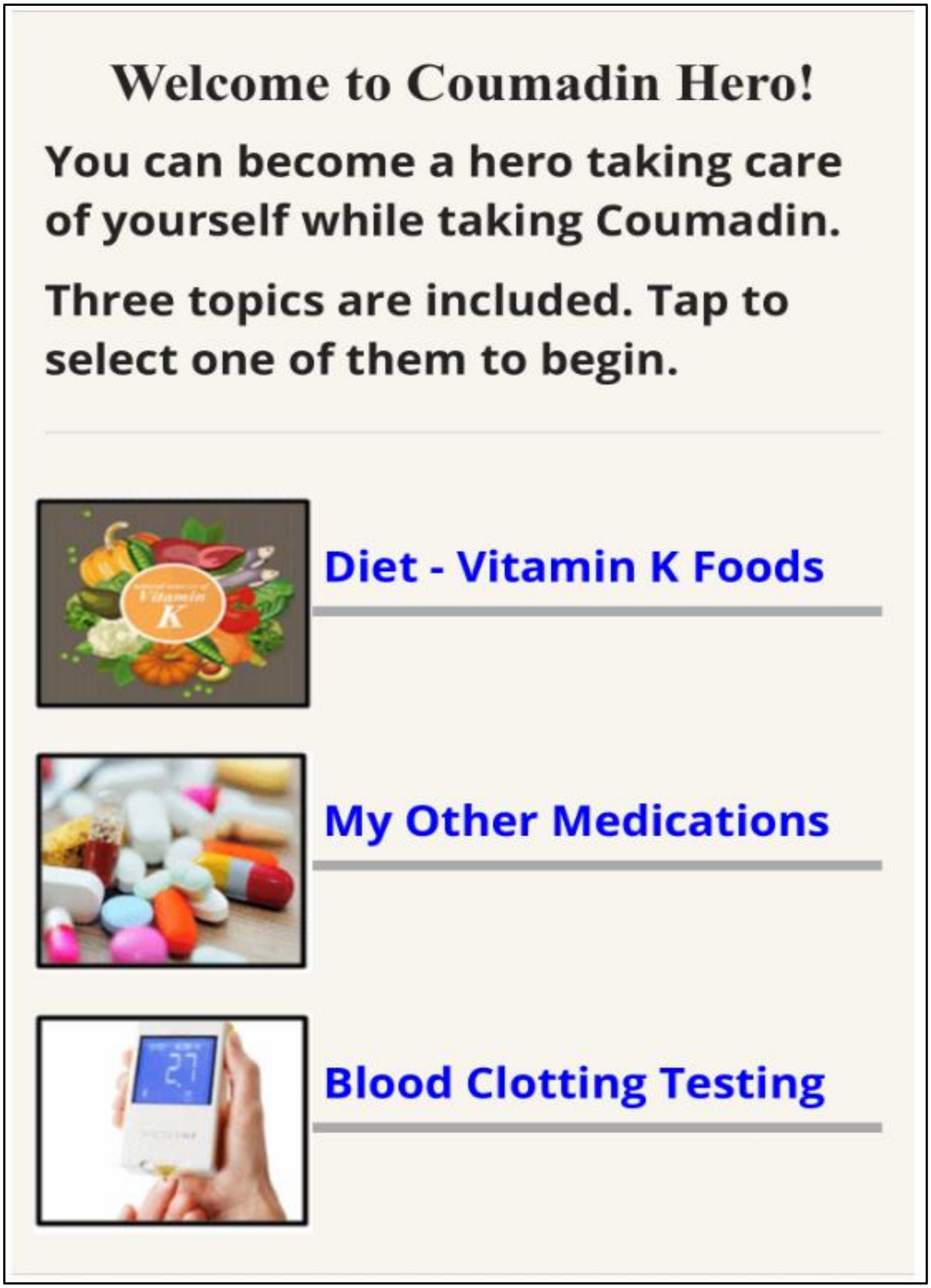


Figure 2.2: Coumadin Hero game landing page

3.1.5. Content summary of the diet - Vitamin k food selection game

Diet – Vitamin K Foods: The Diet – Vitamin K Foods game, will be referred to as "The Diet Game", or "Food Selection Game", and these terms will be used interchangeably. This game is designed to educate patients to watch what they eat and drink since the food they select as the potential to affect how Warfarin works in the body. The goal of this game is to ensure that the patient can identify high and low Vitamin K food items. For the purposes of this game, only the extreme high Vitamin K foods (e.g., kale, broccoli, asparagus, brussel sprouts) and extreme low Vitamin K foods (e.g., carrots, fresh orange, potatoes) were selected to build the game scenarios. Patients must remember that Vitamin K is an essential part of the body's clotting process. Too much vitamin K in the diet can lower the effect of Warfarin. The game consists of 25 food items with different levels of Vitamin K. The foods are randomly selected and presented to the user one at a time during game play. There are 10 foods with high Vitamin K and 15 foods with low Vitamin K levels. The high proportion of low Vitamin K food items was designed to ensure patients are aware of the most common foods available in the local groceries shops that may appear to contain high Vitamin K. Figure 3.3 shows the pool of all 25 food items, selected from the United States Agricultural Research Service's Food Composition Databases of Department of Agriculture (USDA, 2006).

3.1.6. Gameplay (*Diet – Vitamin K game*)

The Diet game is loaded and displayed by selecting or tapping on the icon or link "Diet – Vitamin K Foods" from the landing page (Figure 3.2). The first two screens of the game provide the user with game instructions (Appendix A-1 and A-2). The first screen provides the user information on "Things to Note When Taking Coumadin" with emphasis on the interaction between Warfarin and Vitamin K. The user can advance to the second screen by using the “Next” button at the bottom of the first screen. The second instructions screen gives information about how to play the game, such as, how to respond to an item, how to earn game points, and play time. The user advances to the gameplay screen (Appendix A-3) by tapping the “Play” button. The gameplay screen consists of the following:

1. Game and item clocks – the game clock displays the total game time of 10 minutes per game session. The item clock is set to 60 seconds per item within which the user should select their response to the item. Both the game and item clocks count down as the user plays the game. The user is not given the option to stop or pause the game clock once it starts.
2. The avatar – the avatar points to the food item displayed and asks the user to determine whether the food item contains high or low Vitamin K.
3. The food item image/icon – the food item is displayed in a form of an icon or a picture of the item. The name of the food item is boldly displayed beneath the image.
4. High/low buttons – these buttons appear below the item name with a text instruction asking the user to tap on one of them to determine whether the food item is high or low in Vitamin K.

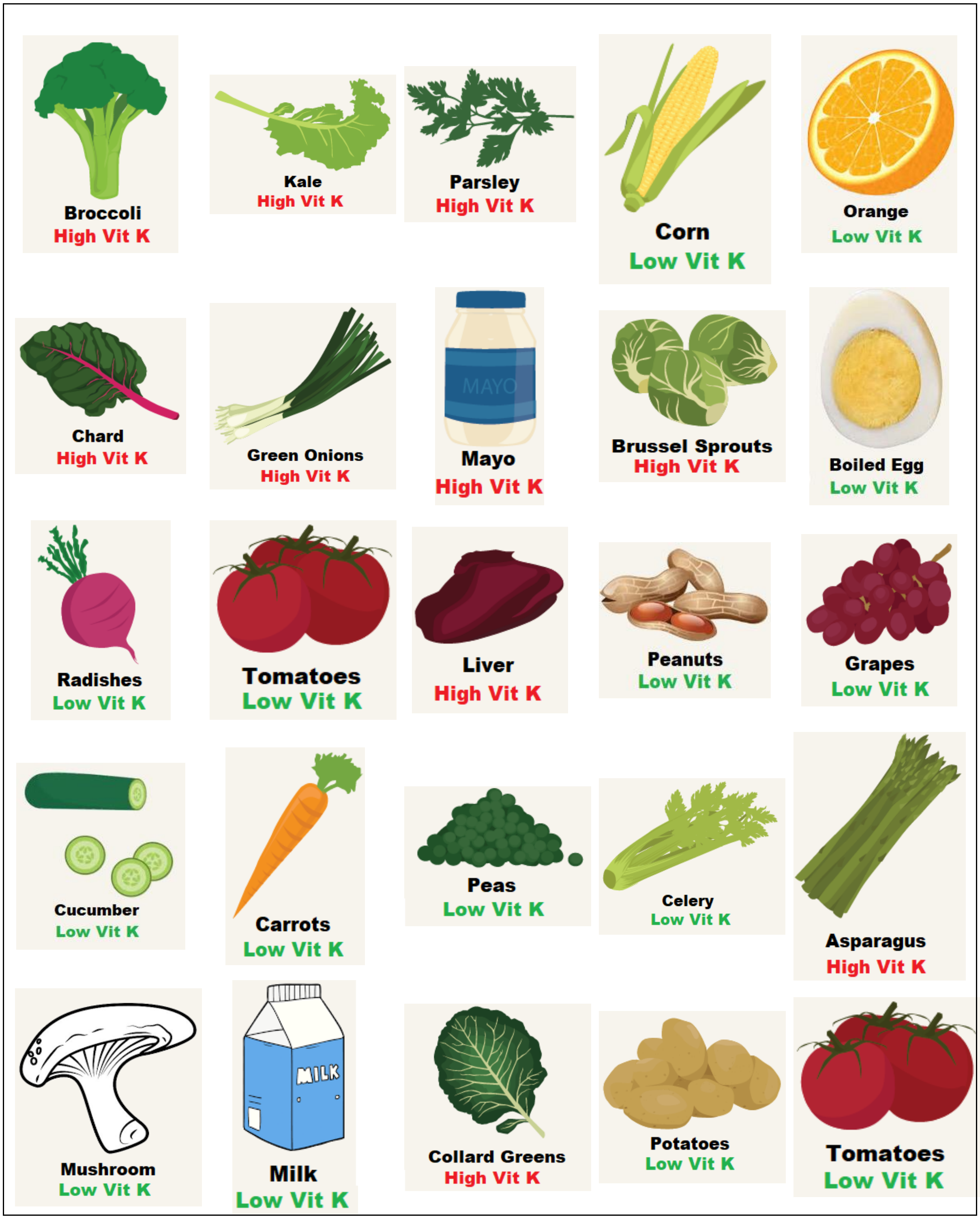


Figure 3.3: The food bank – the food selection is drawn from this pool of 25 food items

3.1.7. Rules and mechanics of the gameplay and scoring

The rules of the gameplay are:

- The food items are randomly presented one at the time.
- At least 10 food items are presented to the user in one game session.
- Food item(s) previously presented in the current session may be repeated but not in a successive order.
- When the user correctly identifies the food as high or low, one point is earned. Instant positive feedback image is displayed (Appendix A-5).
- When the user makes a wrong selection, no point is lost. The user maintains the same number of points already awarded. The game is designed this way to encourage users to play but not to punish and discourage them. Instant negative feedback image is displayed (Appendix A-6).
- When an item is presented, the user has 60 seconds to respond. The user is not able to proceed without responding to an item. If the user fails to select within 60 seconds, the user is given the option to retry or skip (Appendix A-7). The retry option gives the user another 60 seconds to respond. The maximum retry attempts is two, after which the user is forced to respond or quit playing. When the user skips, the food item will disappear and the next item in the queue will be presented. If the user did not skip or retry, the game session will end and return to the home screen (Figure 3.2).

Winning criteria: The user wins the game when they accumulate a minimum of 10 points by correctly identifying 10 food items as having high or low Vitamin K within the 10-minute game session. When the user earns 10 points in less than 10 minutes, they have the option to continue to play and make more selections or end the game and win with 10 points. When the user chooses to continue, they could win the game with more than 10 points. The user can win additional 10 points by correctly responding to 10 more food items. It should be noted that, after the initial 10 points, the user is prompted and given the option to exit and win the game with 15 points. This will continue until a maximum of 20 points is earned and the user will be forced to end the game. The 'Winner's Trophy' will display when the user wins the game (Appendix A-8). When the user wins the game and the trophy is presented, the user has the option to replay or quit the game.

If the user does not earn 10 points in 10 minutes, a message will display as (Appendix A-9) "*You do not have 10 points to win the game. Tap the Replay button to try again*." The user can replay or end the game by using the Replay and Exit buttons. When the user chooses to replay, the game refreshes, the clocks resets, and the food items are randomly displayed one at a time. When the user exits the game, they are returned to the home page.

Captured background data: The gameplay activity of the user was captured and stored on a secured remote server. The user activity that was captured included:

- User ID
- Total play time
- Total number of foods selected (right + wrong)
- Total number of wrong foods selected
- Total number of correct foods selected
- Game results (Win/Lose)

3.1.8. Timeframe of app development

The actual app development time was estimated to be about six to eight months. The software development underwent several revisions and iterations. There were periods of delays due to time and other logistics constraints on the software development team. The app content development document was completed within three months and all exploratory work and wireframes for the software development were completed by the vendor within two months. The first prototype with full functionality of the *Diet – Vitamin K Foods* game was completed in August 2018 and a demo of the prototype was shown in November 2018. The prototype was approved by the dissertation committee with several recommended changes and revisions. These changes were implemented, and the final version of the app with full functionality was completed in June of 2019.

3.2. Evaluation of the app

In this study, usability testing of the app was carried out in two phases of testing – Phase 1 and Phase 2. Phase 1 involved heuristics evaluation of the app where experts looked for specific issues of the app. These experts were faculty members with knowledge in human factors, apps development, and systems design. Phase 2 of the usability testing included pilot and full user testing. The pilot testing used a smaller sample of five people taking Warfarin. The goal of the pilot testing was to identify usability problems that can be addressed before testing on a larger sample. The full user testing involved a larger sample of people who were newly taking Warfarin. The larger sample included the pilot sample because no major issues were discovered to cause the results of the pilot testing to contaminate the result, so the results of the pilot testing was not discarded.

3.2.1. Heuristic testing

Keeping in mind Nielsen's (1993) heuristics checklist, the heuristic evaluators used a list of relevant usability characteristics in reviewing the interface, the usability, or the design. The evaluators who were knowledgeable clinician, described below, were asked to use the adaptation of Nielsen's (1993) heuristics checklist to indicate their level of agreement or disagreement with each statement/item on a scale of 1-5 (1 = strongly disagree, 5=strongly agree) or use N/A for items that were not applicable. The evaluators had the freedom and option to add comments (if desired) by typing in comment fields provided. The last two questions (23 and 24) on the instrument was designed for them to express what they liked about the game and how it could be improved. Instructions for heuristics evaluators is presented in Appendix B, including the Heuristics evaluation checklist (Table 1), which was completed by each evaluator. The task of this group was to identify specific areas in which the Coumadin Hero app violated usability characteristics.

Usability characteristics were grouped under appearance/aesthetics, content, navigation, ease of use and satisfaction, as well as other general characteristics, such as the user's perception of the information presented. The results of the heuristic testing were used to make the necessary additional changes before the user testing. The results were also used to revise the app design in accordance with the violated usability principles. As a first step, the heuristic experts were debriefed in a post-heuristic evaluation session. The researcher had a one-on-one session with each of the three evaluators in a brainstorming mode primarily focused on discussions on possible revisions and redesigns to correct the usability issues identified. The debriefing sessions also provided an opportunity to discuss the positive aspects of the app and reinforced those features where necessary.

3.2.2. Background of heuristics experts

Ron J. Piscotty, PhD, RN-BC, FAMIA: Assistant Professor of the UMSON Informatics program. His research interest centers around the impact that healthcare information technologies have on nursing practice and quality and safety in hospital settings. Dr. Piscotty has worked on several electronic patient applications and is currently working on examining the impact that electronic patient care reminders have on patient care omissions in acute care.

Mary Regan, PhD, RN: Associate Professor at the University of Maryland School of Nursing. She has specific training and expertise in bio informatics with interest in usability testing and Mobile Health applications to promote health. She has been the PI on many State-funded grants and has received NIH funding for grants.

Karen Clark, PhD, RN: Assistant Professor at the UMSON and an advocate for using technology and simulation to advance teaching and learning. She is the current chair of the Technology Advisory Committee of the UMSON. Expert three worked on several healthcare applications including a research study in data collection from electronic medical records.

3.2.3. Heuristics evaluation results and recommendations

After reviewing and consolidating the results from the heuristics testing, 24 usability problems in the app were identified by the three evaluators. Tables summarizing the satisfaction scores and usability problems identified are in Appendix B.

Using the Nielsen's (1999) usability checklist, the mean and median satisfaction score was 4 (Agree) out of 5 (Strongly agree) on the satisfaction scale.

Of the 24 problems, nine were given very low severity ratings and were deemed as "cosmetic problems". These included issues such as inconsistent naming of buttons, spelling errors, poor sentence structure, inconsistent font size, and screen contrast. These issues are highlighted in green in Appendix B Table 2, and were addressed in the revised design. Five usability problems were rated as medium severity (highlighted in yellow) and ten usability problems were rated as major (highlighted in red). These ten usability problems rated as medium or major were further consolidated into three categories: navigation, aesthetics, and confusing directions/instructions to the user. These problems and the suggestions from the evaluators to fix them are discussed below.

a) Navigation issues: On the main screen, the evaluators expressed concern about the navigation buttons. One evaluator stated the navigation buttons at the top of the page were obscured. Another evaluator reported that there was a header navigation bar but no breadcrumbs which made it difficult to know where the user is in relation to the main page. One evaluator offered a suggestion by stating that "it might be nice if you didn't have to scroll down, but I understand the audience may need a larger font. Maybe have a flashing arrow to denote there is more text"

b) Aesthetic issues: All three evaluators expressed serious concerns on several aesthetic features. One evaluator pointed out that "the flashing directions when putting food on the plate is distracting. It is also hard to read because it flashes quickly. The flashing further obscures the navigation buttons. The flashing banner is also distracting and covers information." Another evaluator stated that the blinking instructions were problematic and defeat the purpose of the app. One evaluator bluntly stated the flushing banner is annoying and distracting.

c) Unclear instructions: All the evaluators noticed one or two instructions and directions that lack clarity or were confusing. One evaluator made a critical observation as follows: "The icon on the first page appears to be all vegetables, and some of the text in the directions mentions vegetables, so when I got to the actual game, I was confused a bit to see the 'Liver', it just seemed out of place." One evaluator stated "I'm not sure what you mean about 'game link' but I selected the 'more info' button and couldn't get back and the option on the buttons is too lengthy and not clear." Other comments from the evaluators include – "this item is written incorrectly", "content needs to be written in a way that is more accessible", and "screen almost too bright".

The main changes to the app based on analysis of the usability problems presented above included:

1. Well defined buttons and links that are easy to access on all screens.
2. Replaced the navigation bar with a landing page that has separate links and icons representing the three games in the app.

3. Replaced the flashing and blinking instructions with static and easy-to-read screens that can be advanced with a ‘Next’ button. This effectively replaced the scroll bars that the evaluators were not comfortable with.
4. Revised and corrected the game instructions for grammar ambiguous statements to make them clear.
5. Infographics were added to present the information quickly and clearly. The advantage of using the infographics is that it improves cognition of the user by utilizing graphics to enhance the visuals of the users.
6. Changes were made in the presentation/processing of the food items.
    a. Instead of drag-and-drop by the user, the food items are presented randomly on the screen without user intervention.
    b. The user has the option to skip or retry when the item clock expired.
    c. The user can select the More Info button any time during game play to learn more about Coumadin and/or Vitamin K foods.
7. Changes were made in the scoring and winning parameters. The user earned points by making the correct selection but not penalized when the wrong selection is made. The rationale for this is to encourage play and offer positive reinforcement and feedback to drive the user to try to play more of the game.

3.2.4. Usability testing with patients taking Warfarin

After the heuristics testing, the app was pilot tested with five actual users from the ATC. (The initial pilot and the full usability testing used the same setting, instruments, and consent form as described below). Once consent was obtained, the usability testing with the patient began. The first step of the process was to provide an overview of the evaluation process and answer questions the user might have. Next, a brief tutorial was given to introduce the app. The purpose of this was to decrease individual variability and to ensure all the participants had the same information about the app since none of them had seen the app prior to the day they were recruited. The testing took place in a private consulting room at the ATC.

The patients could interact with the app on their own to get familiar with it for about five minutes. The usability testing involved the participant playing the game based on the game rules already described under the game play section. The researcher usually remained in the room for the entire duration of the game session, in case the user had questions. The screen activities of the game play were recoded and the data accuracy was assessed by the researcher. The average time to complete playing the game was about 10 minutes. The pilot demonstrated that participants could be recruited, follow instructions, navigate the game, and successfully complete the surveys. The researcher compared the first five participants with the last 20 and there were minimal differences, therefore the data from the pilot testing was included in the analysis of the study.

3.3. Setting

The participants were recruited from an Anticoagulation Clinic (ATC) of a major University in the Mid-Atlantic region. The ATC is an outpatient clinic that manages patients on warfarin. Any healthcare provider (regardless of the discipline) can refer a patient to the clinic. In general, however, these referrals are more likely to be people that need help in management, or at least, have been started on Warfarin. It is important to note that referred patients may be at higher risk for medication mismanagement and needing support in self-care.

The ATC clinic treats a variety of thromboembolic disorders such as DVT/PE, atrial fibrillation, stroke, mechanical heart valves, and post-transplant care. The clinic is primarily run by pharmacists and nurses and operates under the Department of Internal Medicine.

If a patient is referred from the Medical Center while admitted to the hospital, the pharmacy team typically educates the patient before discharge. If this does not occur, then the ATC pharmacists educate them during the first appointment at the ATC clinic. During this first appointment, the focus is on three main educational areas: a) reason for warfarin, b) drug and diet interactions, and, c) when to seek medical attention. It is common to focus on other topics, depending on the patient. For example, a patient may have been educated previously, but struggles with the dietary portion. The emphasis will be on diet education for this patient. Another example is when the patient is very concerned about bleeding, so the pharmacists spend majority of the time focusing on this area. All this education information is documented in the patient note in the ATC's Epic electronic health record (EHR). After the education process is completed, the pharmacists provide the patients with the same Warfarin education handouts including information on Vitamin K foods. When the patients come back for their second appointment, the pharmacists may re-educate them, if required. Alternatively, the focus may be on an area where the patient demonstrates a lack of understanding.

3.4. Sample and recruitment

The study used a convenience sample, including the five for the pilot and 20 additional patients for the full usability testing. Usability tests recommend at least 20 participants (Nielsen, 1999). Inclusion criteria for participation in this study include, that patients in ATC clinic:

- be a new referral or currently on Warfarin therapy and need additional education
- be 50 years and older
- be able to read and write English
- have no evidence of vision, dexterity, or mental dysfunction
- be able and willing to independently use the app on a mobile device such as iPhone or iPad (provided by researcher) and complete a survey.

The ATC clinical pharmacist first identified patients as suitable for the study. Eligibility was verified at the time of recruitment based on the patients' medical records and patient self-reports. Identified patients who expressed interest in participating were given a detailed description of the study. Participants were not required to own or have access to a mobile device (iPhones and iPads) to be eligible since they were provided with the device during the testing period. The pharmacists who identified appropriate patients at the ATC verified eligibility and placed them in a private consulting room where the researcher provided them with study information sheets. The researcher informed potential patients about what was required for the study. All consents were obtained by the researcher.

3.5. Data collection/measures

Immediately following the game session, a set of instruments were administered. Data collection included patients' demographic information (Appendix C), computer literacy and technology use (Appendix D), and usability testing of the app (Appendix E). Demographics were collected to describe the sample but also variation in usability was examined by patient demographics. Computer literacy is also a potential covariate to consider in evaluating usability. The questionnaire on Computer Literacy and Technology Use Survey (CLTUS) was adapted from Georgsson and Staggers (2016). This questionnaire consists of 14 items on a 4-point Likert scale related to computer-/IT knowledge, web and mobile services usage, and user experience with the Internet and mobile health systems. Two of the 14 items are open-ended questions related to the level of satisfaction of mobile health systems. The questionnaire was modified and reduced to eight items. Questions related to texting, phone calls, and items considered as duplicates were eliminated. The language of the questions was changed to reflect app usage where applicable. To facilitate the analysis in the small sample, responses 'High' or 'Medium' on how participants rated their level of IT knowledge was described as "High Computer/IT Knowledge" while 'Small' or 'None' was described as "Low Computer/IT Knowledge". Similarly, participants who indicated they use electronic devices either 'Every day' or 'Several times a week' were defined as having "High Computer/IT Knowledge" while 'Once in a while' or 'Never' was described as "Low Computer/IT Knowledge". These "High" and "Low" responses were operationalized in the analysis in Chapter 4.

Based on the TAM model introduced in Chapter 1, three main concepts were examined: intention to use (ITU), perceived usefulness (PU), and perceived ease of use (PEOU). The Perceived Health Web Site Usability Questionnaire [PHWSUQ (Nahm et al., 2006)] was developed to assess website usability, but can be adopted to mobile applications with slight modifications. Permission was obtained from the author to do so. The PHWSUQ instrument consists of 12 items on a 7-point Likert scale related to three subscales: satisfaction, ease of use, and usefulness (Appendix E). The scale ranged from Very unsatisfied ("1") to Very satisfied ("7"). For this study, the instrument was modified to include one additional subscale – intention to use, rather than actual use. Question 6 (Quality of video information) was also deleted since it is not applicable to this study. In addition, the wording of the items was modified for the app evaluation. For the original tool, the alpha coefficients of the subscales, Satisfaction, Ease-of-Use, Usefulness, and the overall scale ranged from .64 - .92. Responses are averaged for each component and across all items, with higher scores indicating greater satisfaction, greater ease of use, greater usefulness, and greater overall usability of the App intervention, respectively. For ease of analysis in the small sample, scores 5-7 on the subscales was described as "High Satisfaction or Agreement" while 1-4 was described as "Low satisfaction or Agreement" These responses were used in the analysis in Chapter 4. The result of the CLTUS is described/interpreted qualitatively in terms of the percentage of users who described their level of computer or IT knowledge or frequency of computer usage as high.

3.6. Data analysis

Descriptive statistics were used to analyze the results and responses of the Computer Literacy and Technology Use, usability and demographic survey questionnaires. The small sample size limited the use of parametric statistics that require normality of distributions and homogeneity of variances. Summary statistics are described for each questionnaire (demographics, computer literacy, and PHWSUQ). In addition, variation by demographic characteristics are examined with bivariate statistics appropriate to the level of measures. Chi-Square test of independence was used to determine association between categorical variables. Associations among satisfaction, ease of use, intention to use, and usefulness were examined with nonparametric measures, while associations among time spent on app, total foods selected, and percentage correct were assessed with Pearson correlation.

3.7. Human subject protection

Permission to conduct this study was obtained through the Institutional Review Board (IRB) of the University of Maryland. Participation was voluntary and participants were fully informed before signing a consent form. They were informed of their right to withdraw their consent at any time without any negative consequences. The participants were informed that if they withdrew, the researcher will not ask for the $20 gift card back unless the participant volunteers to give it back. They were assured that they can stop participating in the study at any time and that this will have no bearing on their care. The researcher was present the entire time during gameplay. The primary risks to patients through participation are loss of privacy, confidentiality, fatigue, and frustration. A copy of the consent approval letter is in Appendix F.

Participants were informed that data about their gameplay activity and demographic information were being collected on a secure, password-protected server. To protect patient confidentiality, pseudo identifiers were assigned to all the participants' computerized records. When the paper version of the survey questionnaire was completed, the following steps were taken to ensure the patients' data are secured and confidential:

1) Did not use names on questionnaires, rather assigned codes that link to the patient identification.
2) Kept a separate document that linked the study code to subjects' identifying information.
3) Kept all documents in a locked cabinet and restricted access to this document to the researcher only or by the committee chair if requested.
4) Kept all electronic files in de-identified form and on password protected server.

Chapter 4. Findings

4.0. Overview of results

This chapter presents the analyses of and findings from the user testing and usability data of the Coumadin Hero game app. After a summary of sample characteristics and baseline computer knowledge and use, results of the game play are presented and then variations by participant characteristics are examined. The last section reports on participant usability.

4.1. Sample characteristics

An overview of the study participant characteristics is presented in Table 4.1. Out of the 25 participants, 12 (48%) were between 50-59 years, 10 (40%) were between 60-69 years, and three (12%) were over the age of 70 years. The majority of the participants (64%) were females. The participants were primarily (84%) of black or African American descent. Most individuals' (68%) highest level of formal education was high school; 20% graduated from college, and 12% had less than high school education. Most individuals (60%) said they lived alone when describing their living situation. Nearly all the participants (92%) had health insurance.

With regard to clinical characteristics, most (88%) had been taking Warfarin for more than one year. When asked whether or not they ever forgot to take their Warfarin, the responses were evenly split with a slight majority (48%) who said they never forgot taking their Warfarin, while 44% said they had; eight percent could not recall. Out of the 10

Table 4.1 Demographic characteristics of study participants (N=25)

	N (%)
Age	
50-59	12 (48)
60-69	10 (40)
70 and over	3 (12)
Sex	
Male	9 (36)
Female	16 (64)
Race	
Black/African American	21 (84)
White	2 (8)
Hispanic	1 (4)
Asian	1 (4)
Education	
Less than High School	3 (12)
High School and above	17 (68)
College	5 (20)
Living Situation	
Live alone	15 (60)
Live with family/friend	10 (40)
Insurance	
Insured	23 (92)
Uninsured	2 (8)
Comorbidities[1]	
Stroke	3 (12)
DVT[2]	9 (36)
Blood clot	11 (44)
Diabetes	9 (36)
Hypertension	15 (60)
Arthritis	13 (52)
Heart failure	4 (16)
Afib	8 (32)
Cancer	9 (36)
Years on Warfarin	
Less than 1 year	3 (12)
More than 1 year	22 (88)
Forgot taking Warfarin	
Yes	11 (44)
No	12 (48)
Don’t recall	2 (8)

Note. Not mutually exclusive so individuals could have multiple comorbidities. 2. DVT – Deep Vein Thrombosis comorbidities listed, the most often cited was hypertension (60%), followed by arthritis (52%), blood clot (44%), diabetes (36%), DVT (36%), cancer (36%), atrial fibrillation (32%), heart failure (16%), and stroke (12%). It should be noted here that these percentages were calculated in respect to each individual so they could have multiple comorbidities. To simplify the analysis, participants' responses of "High" or "Medium" describing computer/IT knowledge and "Every day" or "Several times a week" describing the frequency of using electronic device were defined as "High". On the contrary, responses of "Small" or "None" of computer/IT knowledge and "Once a while" or "Never" about the frequency of using electronic device were labelled as "Low". Table 4.2 shows that 40% of users described their level of computer/IT knowledge as high while 60% reported frequency of computer usage as high. More than three-fourth (76%) have high mobile phone knowledge, while 56% reported their internet usage as high. Sixty percent rated their frequency of playing video games as high.

Table 4.2 IT/computer knowledge of participants (N=25)

	N (%)
Computer/IT Knowledge	
High	10 (40)
Low	15 (60)
Mobile Phone Knowledge	
High	6 (24)
Low	19 (76)
Frequency of Computer Usage	
High	15 (60)
Low	10 (40)
Frequency of Internet Usage	
High	11 (44)
Low	14 (56)
Frequency of Video Game Usage	
High	15 (60)
Low	10 (40)

4.2. Facilitating conditions

The Anticoagulation Clinic (ATC) where the user testing was conducted is part of a major academic medical center in the Mid-Atlantic region with good, password-protected wireless network (Wi-Fi). Throughout the testing period, there was no network outage or interruptions. Also, the app server and all components and functionalities of the app remained stable during this period. The researcher ensured the doors to the private consulting rooms were always closed to avoid hallway noise coming into the room and to safeguard participants' privacy. The researcher remained in the room with the participants most of the time, in case they had questions or needed assistance navigating the app. There were no interruptions throughout the game play for any of the participants. These facilitating conditions ensured that all the participants successfully completed, at least, one round of the game and were not forced to stop midway due to network or app/server outages. There were three "how to" questions regarding the app usage, and not more than two questions or items were skipped.

4.3. Knowledge of Vitamin K foods

Several measures reflect the level of users' knowledge of common Vitamin K food items. These include play time, total correct scores, and correct responses by individual Vitamin K foods, and are summarized in Table 4.3. The relationship between these variables and technology responses were also examined.

4.3.1. Play time, total presented, and percent correct of participants

Before they started, the users were instructed to play the game, at least once, until they got 10 correct responses in order to have a chance of winning. As Table 4.3 shows, the mean game play time was 191.9 seconds (3.2 minutes). The maximum play time was 332 seconds (5.5 minutes) while the minimum play time was just 95 seconds (1.3 minutes). Many participants chose to keep playing the game after the first round had ended even if they had enough points to win the game, so the time cannot be equated to level of knowledge (assuming those with good knowledge could respond more quickly to questions but may also suggest interest and motivation). For example, examination of the raw data revealed several important points worth noting. Of the two participants with the longest play time, one played one round while the other played two rounds. The two users who spent the most time ranked among the bottom three of all participants in terms of their percent correct, indicating a longer time to decide on an answer. One of the users with the longest play time had the second least number of items presented, reflecting more time to answer question but choosing correct answers.

Table 4.3. Participant's play time, total presented, total/percent correct (N=25)

	Mean	Std. Dev	Median	IQR	Skewness	Kurtosis	Min	Max
Playtime (Sec)	191.9	184.0	184.0	133	.48	-.99	95	332
Total Presented	23.8	23.0	23.0	6.5	1.5	2.9	17	41
Percent Correct	76.0	79.0	79.0	15.5	-1.3	2.0	37	95

Note. Std. Dev = Standard Deviation; IQR = Interquartile Range; Min = Minimum; Max = Maximum

The minimum and maximum number of items presented to any user was 17 and 41, respectively. The game was designed to ensure that participants needed to respond to a minimum of ten food items before they could win the game. For each successive round after the initial one, five additional food items were presented for two additional rounds for a maximum of 20 items. The maximum of 41 items means the user played, at least, two complete game sessions. In much the same way, the minimum score indicates all users successfully completed, at least, one session of the game.

Out of the total participants, no one got all items correct the first time. The highest percent correct was 95 and the lowest was 37. The median percent correct was 79% which indicates that 50% of the participants scored 79 or above. The lowest scoring user had to play the game three times, and needed 41 items to get 15 correct responses. The user with the second lowest percent correct needed 19 items to score the minimum 10 points required to win the game.

4.3.2. Aggregate participants' response to Vitamin K foods presented

Table 4.4 illustrates the percentage correct by the particular food item. Note that these responses are not at the participant level, rather the food level. Kale was the highest correct scoring item with users getting it correct 96% of the time, followed by boiled egg (95%), broccoli (93%), and chard (92%).

The food items with the lowest percentage correct were green onions (46%), followed by mayo (47%), liver (50%), and peas (53%). Since the users were supposed to have received some form of education on Vitamin K foods and their impact on Coumadin, many of them knew green vegetables, in general, contain high levels of Vitamin K. This may explain why three of the top four scoring items were all green vegetables. It is not clear why green onions, a green vegetable, had the highest incorrect responses.

4.3.3. Users characteristics and Vitamin K food knowledge level

To explore if participant characteristics are associated with Vitamin K knowledge, participants' demographic characteristics and Vitamin K food knowledge level (assessed by percent correct) were analyzed. These characteristics were age, education, computer/IT level, and number of years on Warfarin (see Table 4.5). Since the summary data in Table 4.3 shows the percent correct distribution is skewed, a non-parametric statistic test was used.

Table 4.4. Count of total food items correct for all participants

Food Item	Vit K Level (H/L)	Total Correct	Total Incorrect	% Correct
Kale	H	25	1	96
Boiled Egg	L	19	1	95
Broccoli	H	25	2	93
Chard	H	24	2	93
Grapes	L	26	5	84
Collard Greens	H	20	4	84
Corn	L	21	4	84
Potatoes	L	18	4	83
Milk	L	23	6	80
Asparagus	H	21	6	78
Peanuts	L	16	4	76
Mushroom	L	24	8	76
Tomatoes	L	20	7	74
Carrots	L	15	6	73
Brussel Sprouts	H	18	6	72
Cucumber	L	19	8	71
Orange	L	15	6	71
Parsley	H	14	6	71
Radishes	L	16	9	62
Celery	L	19	11	61
Peas	L	10	9	55
Liver	H	12	12	54
Mayo	H	14	16	47
Green Onions	H	11	13	46

Note. Vit K = Vitamin K; H = High; L = Low

In addition, age, education and years on Warfarin levels were collapsed into two categories since the number of participants in some of these sub categories were too small to carry out any meaningful analysis and make any inferences from them.

Chi-square test of independence was used to determine if there were any association between selected user characteristics and knowledge level of Vitamin K foods. Knowledge level of Vitamin K foods was measured by percent correct of the food items scored by the user when they played the game. For the entire sample, the mean percent correct was 76 (SD=2.65) with a range of 37-95. Most of the users scored high as evidenced by a median of 79%. The scores were dichotomized at median (>79) to have two groups to compare by demographic characteristics.

A percent correct of 80 and above was classified as “High Knowledge”. Conversely, a percent correct of less than 80 was classified as “Low Knowledge”. It should be noted that the Chi-square statistic was not reported for gender, education, and years on Warfarin because the assumptions of Chi-square test of independence were violated, especially in relation to the expected minimum cell size assumption.

As Table 4.5 shows, of the 50-59 age category, the percentage of participants in the high knowledge group and the low knowledge group is split evenly at (50%). However, of those 60 years and older, 62% are in the low knowledge group compared to 38% in the high knowledge group. The relationship between age and vitamin K knowledge is not statistically significant. With gender, there were more males (67%) who were in the low knowledge group compared to the high knowledge group. Among the females, the percent in the high and low knowledge groups were equal (50%). Of those who had college education, 80% were in the high knowledge group while 65% of those

Table 4.5. Associations between user characteristics and Vitamin K knowledge

Demographics	< 80% Correct N=14 (Low)		>=80% Correct N=11 (High)		
	N	%	N	%	Chi-Square
Age					
50-59	6	50	6	50	NS
60+	8	62	5	38	
Gender					
Male	6	67	3	33	NT
Female	8	50	8	50	
Education					
HS or below	13	65	7	35	NT
College or above	1	20	4	80	
Computer/IT Knowledge					
High/Med	7	47	8	53	NS
Low	7	70	3	30	
Years on Warfarin					
< 1 year	2	33	1	67	NT
>=1 year	12	55	10	45	

NS: Fisher's Exact Not Significant
NT: Fisher's Exact Not Tested due to assumption violations

with high school education or lower were in the low knowledge group. The percentage of those who described their computer/IT skills as high were almost identical between the high knowledge group (53%) and the low knowledge group (47%). Among those who described their computer/IT skills as low, 70% were in the low knowledge group. Years on warfarin one year and longer showed no major differences in Vitamin K knowledge but 67% of those less than one year on warfarin were in the high knowledge group.

4.3.4. Relationship among elapsed time, total foods selected, total correct, and percent correct

Correlational analyses were used to examine the relationship among users' total play time, total of foods selected, and the percentage of correct responses. Spearman's correlation was used because the sample data has failed the assumption of a parametric approach.

The results of the Spearman's Rho in Table 4.6 indicates a moderate negative linear relationship between the total number of foods selected and the percent correct, which was significant [$r_s(23) = -.44$, $p = .03$]. This results mean that there is enough evidence to suggest the higher the number of food items presented, the lower the number of correct responses. Also, there was a strong significant negative linear relationship between total elapsed time and percent correct scored by the users [$r_s(23) = -.81$, $p < .001$]. The longer the time the user spent playing the game, the lower their percent score. It is plausible to assume that users who struggled to navigate the app and choose a response, spent longer time playing the game and had a lower percentage score either because they did not know the answer or got too nervous and underperformed.

Table 4.6 Correlation among playing metrics (play time, total foods selected, and percent correct)

	Play time	Total Foods	% Correct
Play time			
Total foods	0.24		
% Correct	-.81**	-.44*	

Spearman Rho correlations
*p<.05
**p<.01

4.4. Usability analysis

The goal of the usability testing was to identify functional problems and determine user satisfaction with the Coumadin Hero app. The Perceived Health Website Usability Questionnaire (PHWSUQ) for Older Adults was used to assess the perceptions of the participants. The usability dimensions measured with the PHWSUQ tool were satisfaction, ease of use, and usefulness. As discussed earlier in chapter 3, for this study, the instrument was modified to remove questions on video and included one additional subscale – intention to use -- rather than actual use since the app was not made available to participants outside the testing period. Satisfaction asked about how much the participants like different aspects of the app (e.g., overall quality of graphics). Ease of use measured how the participants found the app easy to learn and use. Usefulness asked about how the participants thought using the app will help them identify high and low Vitamin K foods. The intention to use, rather than actual use, sought to measure self-predicted future usage since the app was not made available to the participants after the user testing.

Users were asked to rate their level of satisfaction on these elements on a 1 to 7 scale with higher scores indicating greater satisfaction with the app, greater ease of using the app, greater usefulness of the app, and greater overall probability of using the app, if made available to them. For ease of analysis in the small sample, scores 5-7 on the subscales was described as “High Satisfaction or Agreement” while 1-4 was described as “Low satisfaction or Agreement”. The responses were dichotomized based on the level of satisfaction or level of agreement (Table 4.7) and to have two groups to compare.

Table 4.7 Participants' responses to usability questionnaire

PHWSUQ Items	High satisfaction or agreement*		Low satisfaction or agreement	
	N	%	N	%
Satisfaction (1-7 satisfaction Likert)				
Ease finding information	17	68	8	32
Ease reading information	19	76	6	24
Overall appearance	18	72	7	28
Overall graphics quality	23	92	2	8
Ease of use (1-7 agreement Likert)				
App easy to use	23	92	2	8
Less mental effort required	24	96	1	4
Overall ease of use	23	96	2	8
Usefulness (1-7 agreement Likert)				
Help understand health problems	20	80	5	20
Help improve health knowledge	22	88	3	12
Help maintain health habits	21	84	4	16
Intention to use (1-7 agreement Likert)				
Intent to use once daily	13	52	12	48
Use app as reminder	16	64	9	36
Intent to use as guide	20	80	5	20

Note. *High satisfaction/agreement responses 5, 6, or 7

As Table 4.7 shows, the percentage of users in the high satisfaction or agreement group for the satisfaction, ease of use and, usefulness subscale items ranged from 68% to 96% signifying some usability problems that will need to be addressed. Generally, the majority of the users were in the high satisfaction or agreement group compared to the low satisfaction or agreement group. This results signify that majority of the participants expressed high level of satisfaction or agreement. Of the three dimensions, ease of use has the highest percentage of users (92 to 96) in the high satisfaction or agreement group. Under usefulness, more than three-fourth (80% to 88%) were in the group that expressed high satisfaction or agreement that the app was useful and could help them improve their knowledge of Vitamin K foods and help make good choices in their food selection. With intention to use, while the users did not have an opportunity to use the app after this usability testing, the majority (52% to 80%) were in the high satisfaction or agreement group compared to the low satisfaction or agreement group. This results suggest that more than half thought they would use the app as a reminder and as a guide if made available to them.

In sum, although it was important to determine the overall satisfaction, ease of use, and usefulness of the app, likewise, it was important to examine the users' satisfaction and agreement scores regarding specific aspects of the app. The overwhelming majority of users (92-96%) expressed high level of satisfaction or agreement that the app was easy to use but scores for certain elements of the usefulness subscale, such as, the overall appearance, ease of reading and finding information were not quite as high (68 – 72%). This means the app was easy to use but further design work to the app may be needed to improve the overall quality.

4.5. User characteristics and usability dimensions

To explore the association among user characteristics and the usability reported above, Chi-square analysis was done. As Table 4.8 shows, the responses of the satisfaction subscale were summed and dichotomized to "Satisfied" and "Unsatisfied". By the same reasoning as in section 4.4, a non-parametric test was used, and the Chi-square statistic was not reported for age, education and years on Warfarin because the assumptions were violated.

Table 4.8 Association between user characteristics and level of satisfaction of app use

Demographics	High Usability/Satisfaction*		Low Usability/Satisfaction		
	N	%	N	%	Chi-Square
Age					
50-59	6	50	6	50	NS
60+	7	54	6	46	
Gender					
Male	4	44	5	56	NS
Female	9	56	7	44	
Education					
HS or below	11	55	9	45	NT
College or above	2	40	3	60	
Computer/IT knowledge					
High/med	8	53	7	47	NS
Low	5	50	5	50	
Years on Warfarin					
< 1 year	2	66	1	33	NT
>=1 year	11	50	11	50	

High usability >80 (median)
NS: Fisher's Exact Not Significant
NT: Fisher's Exact Not Tested due to assumption violations

The results show that satisfaction was moderate for all users. There was no significant association between the selected user characteristics and the satisfaction with the app. For the entire sample, the mean usability score (satisfaction with app) across 25 participants was 78.1 (SD=1.52) and a range of 61-85. Most users scored high as evidenced by the median of 80. The scores were dichotomized at median (>80) to have two groups to compare by demographic characteristics.

In both the younger (50 – 59) and older (60+) populations, the percentage of participants in the high and low usability/satisfaction groups were identical, with a slightly higher percentage (54) for those 60 years and older who were in the high usability/satisfaction group. Among the males and females, the percentage of users in the high and low usability/satisfaction groups were almost identical (44/56 for males and 56/44 for females). There was a low percentage (40) of participants with college degrees who described their usability/satisfaction as high compared to 60% of those with high school diplomas. The lower usability and satisfaction score among those with college degrees may be due to higher expectations compared to those with high school diplomas or below. Under computer/IT knowledge, there were no differences in the percentage of participants in the high and low usability/satisfaction groups. Finally, 66% of participants on Warfarin less than one year described their usability/satisfaction as high compared to those on Warfarin one year or more who were evenly split at 50%.

4.6. Summary of findings

In summary, the facilitating conditions at the study site ensured that all participants successfully completed the study without any interruptions. The average play time of about three and half minutes (192 seconds), was far lower than the ten minutes that the researcher had originally anticipated. While no user answered all the questions correctly the first time, overall, the scores of the majority of the users were very high with a median score of 79%. The highest score was 95% (20 out of 21) and the lowest score was 37% (15 out of 41). The results also show that most of the highest scoring food items were green vegetables ranging from 92% to 96% correct response rate.

With regard to usability, most users were satisfied and found the app useful, and 52-80% expressed intention to use the app if it were made available to them. Analysis of the results also revealed no significant differences between user characteristics and their knowledge on Vitamin K foods. Similarly, there was no association found between user characteristics and level of satisfaction, assessed by the overall satisfaction level of the app. In general, there was limited variability in the usability satisfaction assessment.

Chapter 5. Discussion

5.0. Overview

The results of the study are discussed in this chapter beginning with the app development (Aim 1), followed by discussion of usability testing (Aim 2). Lessons learned from the app development and usability testing, as well as observations from the Anticoagulation (ATC) testing environment will be discussed. The strengths and weaknesses of the study are then discussed before concluding with implications of the study for practice and research.

5.1. Warfarin education using apps

Although a number of direct oral anticoagulants (DOACs) have been approved in the last 10 years, Warfarin has been the most frequently prescribed anticoagulant, and the standard of care to prevent and treat thromboembolic disorders (Dasgupta & Krasowski, 2020). However, information from the *Anticoagulation Desktop Reference* by the Michigan Anticoagulation Quality Improvement Initiative (MAQI) reported that, DOACs are now recommended over warfarin in patients with DVT of the leg or PE (in non-cancer patients) and atrial fibrillation, except in patients with moderate-to-severe mitral stenosis or a mechanical heart valve (Barnes, Haymart, & Alexandris-Souphis, 2020).

Patients on Warfarin must be monitored closely because it is a high-risk medication. It has a narrow therapeutic index/window, outside of which the incidences of thrombotic and hemorrhagic events increase (Zahid et al., 2020; Shuaib et al., 2014). Because Warfarin is a high-alert medication, patient education is often provided with the aim of increasing understanding of the treatment, enhancing self-management skills to reduce complications, and improving the overall health status. However, Warfarin education and management remains challenging. First, education must include multiple aspects of Warfarin care, such as, medication schedule, dietary influences, safety management, and importance of regular clotting testing. Second, Warfarin education is predominantly paper-based and labor-intensive, often using 1:1 education and review sessions. At the time of app development, very few apps were available that are designed for the patients' self-directed learning. One of such apps is called *Vitamin K- iNutrient: Vitamins K1, K1D & K2*. This app provides information about foods' vitamin K content based on preparation and serving sizes. The app is available only on the Apple app store for iPhone and iPad and cost $2.99 to download (Hollender, 2019).

Apart from the app described above, the closest self-directed educational resources were videos and provider websites that give information on Warfarin education. Examples of these are The Johns Hopkins Hospital's Warfarin Guide for Patients and Families (JHU, 2009) and The Mayo Clinic's Warfarin Diet (Mayo Clinic, 2020). Most of the apps currently available are provider-centered, such as, The ATRIUM Anticoagulation Tool by the University of Maryland, Baltimore (UMB) School of Pharmacy that offers personalized dosing recommendations to guide treatment (AppAdvice, 2020).

Patients are generally educated verbally and/or with written materials that usually are passive and not enough specific information to provide the needed education. Warfarin education is further complicated by the increasing complexity of food selection, thus knowing the right quantity or serving size of specific food items presents additional challenges and patients should sometimes refer to food labels [(also known as food charts, JHU, 2009)] to assess the amount of Vitamin K in foods. Generally, green vegetables and fruits contain high Vitamin K levels. However, not all green vegetables and fruits are high in Vitamin K and not all non-green food items are low in Vitamin K.

Consequently, this interactive app was developed to educate patients on what they eat and drink since the type of diet affects how Warfarin works in the body. The app is not meant to be used only for teaching, but as a tool in the form of a game – to help increase their knowledge and guide food choices. The goal is to ensure that the patient can identify high and low Vitamin K food items. The development and testing of Coumadin Hero was a proof of concept study, with the intent of determining if an app based on gamification principles would be useful to people taking Warfarin.

5.2. Coumadin app development and lessons learned

The Coumadin app development was contracted to a small team of software developers although the researcher was responsible for writing the requirements, designing the interface and prototype, as well as conducting the functional and usability testing. The entire software development process spanned over a period of 36 months beginning with requirements analysis and design in the middle of 2016 and completed with user testing in the summer of 2019. The logistics of sourcing out the software development created an added challenge to this project.

Since the app was designed from the ground up, there were several versions of the requirements and prototypes. The prototypes went through three iterations before the dissertation committee approved the fourth version. The contractor's inability to assemble the necessary infrastructure and logistics to develop and host the app on a dedicated secured server also delayed progress. The software development team consisted of three full-time software engineers who do small projects in their spare time. Other challenges related to arranging payments through the university with support the student researcher received from the Maryland Higher Education Commission Nurse Support II Program. In addition, it took about six months to build a secured environment to start working on the software.

The app was designed to work only on Apple's iOS platform. According to a survey by PC Magazine (2019), 54 percent of mobile phone users in the United States have Apple's OS while 42 percent use Android. The remaining four percent falls into other categories, such as Windows and BlackBerry. Although the iOS platform is the favorite, the number of Android users is significant enough to deprive many intended users of the app. This was manifested during the user testing as many participants had Android phone in hand, although they were not expected to use their own personal mobile phones.

Another lesson learned was that the AngularJs® programing language used by the developers, restricted the researcher's ability to customize certain functions and features of the app. Angular is big and complicated compared to html. To make simple changes requires mastering Angular and demands considerable effort beyond the scope and timeline of the project. For example, after the app development had gone past a certain point, the researcher wanted to customize the avatar represented as a young white icon man who played the game. This should have been a customizable feature to give the user the option to select who they wanted to represent (e.g., male/female, Black/White/Latino/Asian, young/old). This was a flaw missed at the design and requirements phases of the development cycle and could not be easily changed. However, asking for changes was considered beyond the scope of work and required additional funding and time that would have delayed the project even further.

5.3. Participants' app usage and Warfarin knowledge – lessons learned

5.3.1. Participants' app usage

The results revealed a relationship between the users' play time and the number of correct responses, which demonstrated that those who spent more time per game session had lower scores. Another observation was an inverse relationship between the number of food items presented and the number of correct responses, although the correlation between the two was moderate. Naturally, users who were presented with more food items had a better chance to come across common food items they can correctly identify (but doesn't necessarily mean they got them correct), compared with users who had fewer items presented to them. However, the lowest scoring users had the highest number of food items presented, and the user who scored the least needed three chances of play sessions to win the game. One possible explanation of such an occurrence could be that, some users who had more food items presented probably were guessing the responses, hence their selections were mostly based on chance. As a result, these users tended to click through and move on to the next item with the hope of finding an easily identifiable food item, and hence, misidentified most of the foods presented to them.

5.3.2. Participants' Warfarin knowledge – lessons learned

In general, the participants showed high knowledge of Warfarin regarding Vitamin K foods in the green vegetables groups. The participants' responses at the food level showed four of the top five food items with a score of more than 90% were green vegetables. These findings suggest many of these patients on Warfarin were already aware green vegetables are high in Vitamin K levels. This is in line with the United States Department of Agriculture (USDA) recommendation which categorized green vegetables as the main sources of Vitamin K (USDA, 2006). This result is consistent with the notion that when patients begin warfarin therapy, baseline education should include information on Vitamin K-rich sources (Nutescu et al., 2006). It is worth noting that over 50% of the foods with a score of 80% or less were green vegetables, including specific examples, such as, green onions and Brussel sprouts, which have high Vitamin K levels. Studies have shown that vegetable consumption is particularly low among African-Americans so this observation is not surprising given that the sample was predominantly (84%) African American (Nicklett & Kadell, 2013).

The analysis of the testing results showed that the older population appeared as having higher Vitamin K knowledge than the younger population. Although this phenomenon could not be statistically tested as part of the study, one possible explanation could be that the older participants were more familiar with Vitamin K foods. Studies have shown that older adults are more likely to eat more servings of fruits and vegetables than younger adults (Nicklett & Kadell, 2013) and, therefore, may have higher knowledge of green vegetables that tend to have high vitamin K levels. They may have been eating most of these common foods for longer and, therefore, become more knowledgeable with their Vitamin K levels (Nicklett & Kadell, 2013; Nutescu et al., 2006).

The results show a higher proportion of high Vitamin K knowledge among female participants. One explanation may be that women are more likely to purchase food and prepare meals, thus may have more food knowledge. The higher knowledge among college educated participants is consistent with the literature as education is one of the major socio-economic factors that determines dietary knowledge coupled with the ability to purchase the right foods because of higher income. Older adults with higher individual and household educational attainment tend to have higher knowledge of what they eat and their daily recommended values of fruits and vegetables (Nicklett & Kadell, 2013).

5.4. Usability testing lessons learned

5.4.1. Heuristics evaluation

Both heuristics evaluation and usability testing were conducted. The heuristics evaluation uncovered numerous potential user issues. The broad category of issues was categorized into navigational, aesthetics, and unclear instructions. The issues and recommendations were substantial to cause the complete overhaul of the app prototype and design. Examples of each category of issues, including those that were considered as general are presented below:

Aesthetics: flashing banners and instructions/directions too distractive, black bolded fonts with white background too hash to the eye.

Navigational: unnecessary scroll bars and the difficulty finding and using navigation bars when present.

Instructions: mismatch or contradictory statements between food icons and text descriptions, as well as unclear, incomplete, or ambiguous texts.
General: inconsistent scoring criteria, lack of feedback to the user when food is selected. It should be noted that the researcher did find studies that have encountered similar problems or issues that have been grouped the same way.

The new design avoided the use of copious text and made better use of infographics to depict information in a clear and concise manner. Another problem was that the heuristics evaluation occurred too late in the app development cycle following three prototypes which contributed to delays in the app design. Nielsen (1993) recommends early evaluation is highly important even if only initial mock-ups are available in the life cycle.

5.4.2. User testing

After the heuristics evaluation, the app was pilot tested with five actual participants from the Anticoagulation (ATC) Clinic from June 18th to June 25th, 2019. This was followed by a full user testing involving a larger sample of 25 people and included the pilot sample since the results of the pilot testing did not show any major user issues. Observations were made related to the general usage of the app as well as the demographic characteristics of the users and their app usage.

Although many changes were made to reduce the amount of text users have to read, it was observed that users spent a considerable amount of time reading two full screens of instructions before they started playing the game. Good user interface for mobile apps should be clear and devoid of texts or icons that directly impact or distract from the app usage. The user should be able to use the app without seeing lengthy tutorials. If the application starts with a lengthy tutorial, it probably suggests a bad design. In most cases, users will decide based on their first experience whether or not they like an app (NCT03273140, 2017). The majority of users always prefer apps to be simple, and most of the time they do not want to read instructions to use any app (Space O Technologies, 2017). During the testing of this application, the researcher observed that some users spent almost the same amount of time reading the instructions as the actual time spent playing the game. This was especially so with respect to participants that appeared frail and slow. The consequence of this was increased testing time per individual, which resulted in the app on the iPhone not being available for other potential participants who had agreed to wait for short periods but had to leave. This situation happened a few times on busy days when users were scheduled back-to-back for testing. The cumulative effect was an increase in the number of days spent on testing and missed opportunities to include other participants who might have found the app useful.

The app has a "More Info" menu button with links to nine different Coumadin related topics, ranging from uses, effects, monitoring, drug interactions, and other concerns of Coumadin. The researcher observed that none of the 25 participants touched this button either out of need or curiosity. The presumption is that either the game was so intuitive for the participants or they were focused on completing the game and did not want additional delays. The time and resources that went into developing this functionality could have been used in some more desirable alternative functions or modules.

The user testing also showed several usability trends with respect to the demographic characteristics of the participants. Regarding the ease of use of the app, the young old

(50-59) participants with better manual dexterity appeared more comfortable and found the app easy to use and navigated the screens more quickly than the middle –old (60-69) and old-old (70 and over) users. In addition to not having grown up with technology, participants over 50 years of age are more likely to have more comorbidities and reduced musculoskeletal coordination and/or general motor impairments (Faisal et al., 2014). Therefore, it is not surprising that the older participants in this study were more likely to be less comfortable and, hence, less satisfied with ease of use.

On the usability scale, most users were generally satisfied with the ease of use, usefulness, and overall satisfaction of the app. The only exception was the intention to use subscale with a score ranging from 52 to 80 percent. This indicates that the participants found the app useful and were receptive to it but did not show the same level of interest in using it if it were made available to them. This may be due to the fact that, since the sample consisted of older adult, their desire to use a mobile app or play an electronic game may not be as high as if the population were much younger. It should be noted, however, that there wasn't much variation on the technology question due to the small sample size. A study of older adults who took part in using an app that helps monitor Vitamin K foods demonstrated positive reactions but they did not think such an app was for them but will rather benefit someone else (Lee et al., 2014).

5.4.3. User testing environment

As already noted in Chapter 4, there were several facilitating conditions that ensured the successful completion of the user testing. The ATC secure conference and individual consulting rooms were used. The researcher ensured these areas where the testing took place were devoid of external noise and distractions from visitors and innocent intruders who may be going about their normal duties. In addition, the incentives likely helped in recruitment. It is worth noting that during the summer of 2019, there was a much bigger study of a similar patient group being conducted at the same clinic, which was not known to the researcher before this study began. The other study paid patients $50 as incentives to participate while a $20 gift card was offered for participating in this study. Although it is difficult to determine the impact on the recruitment, it is safe to assume it probably influenced the willingness of some participants who had already been approached or participated in the other study. Some participants expressed disappointment with the $20 gift card and thought they had received a reduced amount because they heard from other patients that the study was paying $50. Upon further inquiry by the researcher, it turned out that some of the participants were enrolled in both studies and expected the same incentive reward or were confused this study and the other research study were the same.

5.5. Strengths and limitations of the study

5.5.1. Strengths

The Coumadin Hero app was the first one known of its kind. Using nationally recognized dietary recommendations for patients on Warfarin, the app was developed to supplement traditional teaching materials. Built on gamification principles and using established measures, this proof of concept study contributes to the current state of the science of using mobile apps to manage chronic diseases requiring medications that have potential food interactions. As emphasis on self-management and remote disease management increases, people need tools like game apps that are fun to use but convey knowledge that would maximize their self-care.

The survey questionnaire for this study was primarily based on the Perceived Health Website Usability Questionnaire [(PHWSUQ) Nahm et al., 2006] and The Computer Literacy and Technology Use Survey [(CLTUS) Georgsson and Staggers, 2016]. These instrument have been tested in previous studies and have high impact. The PHWSUQ instrument explores the users' experience with applications, including questions about ease of use, whether technical problems were encountered, and whether the information was useful. The CLTUS measured intention to use, rather than actual use. Use of these reliable and valid usability measures supported the validity of the findings of the study.

Furthermore, this study is the first known food app based on gamification principles and run on mobile devices. The Warfarin education tools found are in the form of quizzes, surveys, and interviews (Lee et al., 2014; Shuaib et al., 2014). There are some apps that were designed with different and broad objectives. One of these was developed as a feasibility study called the *Mobile Applications for Seniors to enhance Safe anticoagulation therapy* (MASS). This app is a mobile-based health technology intervention designed to promote independence and self-care (Lee, et al., 2016). There is an app that is focused on Vitamin K food selection which is web-based and does not run on mobile devices (Faddoul et al., 2013). Another app is a commercial product currently being sold on the App Store for iPhone and iPad called *Vitamin K- iNutrients* which provides information about foods' vitamin K content based on preparation and serving sizes (Guadette, 2016; Hollender, 2020). While these Warfarin education tools and/or apps share some of the features of the *Coumadin Hero* app, none of them combines the strengths of gamification principles, using the inherent advantages of mobile devices, and targeted at Vitamin K foods.

Another strength of this study pertaining to the app development is a robust heuristic testing by three professors from the University of Maryland School of Nursing with diverse backgrounds and expertise in usability and mobile applications. The heuristics testing resulted in substantial improvements in the final app design. As noted earlier in this chapter and in chapter 3, the heuristics testing and subsequent recommendations led to improved screen appearance with better graphics, well defined and easy to access buttons, the use of infographics, easy to understand instructions, and better scoring and wining parameters with positive reinforcement that encourage and motivate the users to play more games. The net effect of these improvements was evident during user testing as none of the participants abandoned or quit playing before completing, at least, one game session.

Also, the involvement of clinicians, such as the Pharmacist/Director of the ATC Clinic, in the process of app development was an added advantage. However, the number of health-related apps available for download run in the thousands but very few are appropriate for clinical use regarding patient education. It is difficult for clinicians and patients to identify apps that will add value to patient care since the standards for approval of apps vary across multiple settings (Rowland et al., 2020). It is important that medical professionals and clinicians who recommend apps for patients are knowledgeable of the content and appropriateness for target patients. For example, reading level may be too high or the content too extensive or irrelevant. Therefore, it is important for knowledgeable people, such as content and usability experts to be involved in the app development (Tang et al., 2018) but clinicians such as, pharmacists and nurses do the actual teaching.

Another important strength is that the sample inclusion criteria were broad, and 88% of the patients had been on Warfarin for more than a year. Thus, they likely had received varied amounts of instruction on Vitamin K foods, which likely influenced the knowledge results and their willingness to test the app. Yet, there was good diversity in terms of gender, age, and education.

The diversity of the sample in terms of gender, race, and socioeconomic status is also a strength. The predominantly African-American sample (84%) reflects the population of the city where the study was conducted. African-American patients have a significantly higher rate of venous and other thromboembolic diseases, and are twice as likely to suffer and die from stroke compared to Caucasian and other racial groups (Buckner and Key, 2012; White and Keenan, 2009; Trimble, & Morgenstern, 2008). Therefore, this racial group is more likely to be on Warfarin therapy (White & Keenan, 2009). Interventions aimed at Warfarin education should focus on knowledge-building among African-American adults who are more likely to be among the socially and economically vulnerable (Nicklett & Kadell, 2013). Consequently, the study captured the population most likely to benefit from using the app.

One significant strength is that the app could be used to address some of the social determinants of health (SDOH) that may be represented in people on Warfarin. As health care is more focused now on population health, data outside of traditional clinical findings provide comprehensive view on patient's health status and provide better strategies to improving the effectiveness of their care (Cantor & Thorpe, 2018). It is now universally accepted that patient's SDOH needs to be addressed to ensure successful outcome of health interventions, such as the use of health apps to address specific patient disease condition. These factors include individual's financial situation, ability to get healthy food options, ability to get reliable digital devices such as smartphones, and education level. The SDOHs can be more important to an individual's health outcomes than the actual clinical intervention they receive. Available statistics show that clinical care influences just 10 to 20 percent of a patient's outcomes, while social determinants of health impact the remainder (Sokol, 2020). It is imperative to do social needs screening and social needs intervention to ensure the target population benefit from health apps such as this project. For example, outcomes will not improve for a DVT patient on Warfarin, if they cannot afford healthy food options with the appropriate level of Vitamin K or get to a grocery store miles away from home. In much the same way, if a patient cannot afford a smartphone device on which the app runs, then one may question the relevance of the app.

The evolution of health apps has largely depended on the widespread use of smartphones. The growth in smartphone usage and prevalence of health apps adoption usually go in the same direction (Chmielarz, 2020). To ensure better outcomes for apps, such as *Coumadin Hero*, there is the need to integrate patient-level screening about these social risk factors, and other patient characteristics and use the information to customize the app. For SDOH to be incorporated, the app should be designed to, first, provide the option to select which risk factors to screen, and then focus on which of them are addressable. That information could be captured at the server level and integrated with other databases that detail appropriate local and community resources, make a referral and follow-up. These types of platforms are developing at the community level to easily identify and refer patients to social service organizations (Cartier, Fichtenberg & Gottlieb 2019).

5.5.2. Limitations

Several limitations of this study have already been described. One of the main study challenges was the difficulty in recruiting study participants from the ATC clinic. While patients received a $20 gift card at the end of participation, patients were unwilling to devote the 20-30 minutes required even though the risk is low. Furthermore, the incentives provided to participants were inadequate. During the data collection period, the researcher found that there was a parallel and concurrent study at the same ATC site using the same pool of patients. The other study was paying $50 as incentives compared to the $20 gift card. Another issue was the difficulty with the app technology with participants who were older and didn’t have the basic skills to navigate the game screens and interfaces. Establishing rapport with potential study participants was essential and required dedicated time at the ATC. As a project with limited funding, the design of the app was contracted to consultants whose primary work is not app development. This situation resulted in additional delays and the use of some technologies that were not easily adaptable to the rapid changes required based, in part, on the heuristics testing results.

Related to the design, the small sample size was appropriate for this pilot study, but it limited the statistical power and sample adequacy to detect differences. Additional limitations include those usually found with non-probability sampling, which includes the inability to know how well the sample represented the target population. Another limitation might be that the participants had been on Warfarin for varied times and did not provide a baseline for measuring knowledge on Warfarin and Vitamin K foods. Participants had received previous instructions on Vitamin K foods – and some may have received instruction and materials multiple times.

Design related limitations also include the effort and willingness of participants to spend time to fully explore the app and complete the survey. Some seemed primarily interested in the incentive and moved through the game quickly and responded randomly to the Likert items. Perhaps they believed this was what the researcher desired, an example of potential social desirability bias.

Another set of limitations of the study relate to the app. First, the lack of functionality of the app to capture the differences in Vitamin K levels depending on whether a particular food is in raw, cooked, and/or processed form was identified. Not only that, the app was not designed to account for information on serving sizes of various food items. Food's vitamin K content varies based on its preparation (Gaudette, 2016). For example, while a cup of raw spinach contains 145 micrograms (µg) of Vitamin K, a canned spinach of the same quantity contains 988µg; and while one cup of cooked kale has 1062µg, there is 1147µg when the same amount was first frozen before it was cooked (Netescu et al., 2006). The depth and complexity of adding this functionality to the app design was beyond the purview of this project considering the time and financial implications of such an addition.

Additionally, the app design primarily focused on common green vegetables and fruits available in local grocery shops that are known to contain Vitamin K. When the food bank was created, information was collected from the patient education material used by the University of Maryland Medical Center Antithrombotic Clinic (UMMS/ATC) without regard to which population or food items the list was tailored for. However, it was discovered later in the process that the list missed some foods that could adversely interact with Warfarin, not because of their Vitamin K content but their antiplatelet properties that could interfere with INR levels. One important example is cranberry juice. The United Kingdom's Committee on Safety of Medicines (UK/CSM) found 12 cases that involved increased and unstable INR of patients who were on Warfarin and consumed cranberry juice. The adverse reactions were due to the antiplatelet effect of cranberry juice that increased bleeding risk. The UK/CSM advised that patients taking Warfarin should avoid consumption of cranberry juice and cranberry capsules/concentrates. If there is a medical necessity for cranberry juice, they should be closely monitored during concurrent use. Other food items have had adverse effects on people on Warfarin due to their antiplatelet properties. These foods include, but are not limited to, grapefruit, dietary and herbal supplements such as, garlic, ginger roots, and Gingko biloba (Netescu et al., 2006). The major take away from these missed/omitted food items is that future study designs should consider all intakes, including supplements.

A better approach to have a good measurement of what the participants consume would be asking them if they were thinking of some foods that they regularly eat that were not on the food items presented. In effect, the app wasn't culturally appropriate for the population and didn't have what may be more culturally appropriate foods. Alternatively, the researcher could have asked the participants some open-ended questions on the survey questionnaire to name some of the most common foods that they buy and compare with the food bank for this study. There may be foods common to the sample that the study did not include, and hence, threatens the internal validity of the study as whether the pool of food items selected were sufficient to measure the sample's knowledge on Vitamin K foods. Thus, the generalizability of the app and study findings is also a concern. The generalizability of the app to other Warfarin users and other medications cannot be well understood. Therefore, for generalizability, similar studies should be conducted with diverse samples and different set of foods. These questions regarding foods and sample needs to be captured in future study designs.

Considering the look and feel of the app, the avatar of the game was a young white man, although the participants were predominantly black, female, and older. This contradicts good functional design. The avatar feature which should have been customizable to give the users the option to choose, was missed at the design stage and was too late to change when it became a noticeable concern during heuristics testing. As noted earlier in this chapter, customizable features for individual users to choose what suits their personalities or who they wanted to be would be preferable and should be seriously considered in any future design.

Lastly, out of the initial three games modules proposed, the research only focused on one of them due to limited development resources. The original plans were to develop an app with three mini-games focused on diet, medication safety, and PT/INR testing. However, after some preliminary and exploratory work, the researcher decided to devote the limited resources to develop only the *Diet – Vitamin K Game.* The contractual agreement with the software development team had a timeframe that could not be extended, which added extra pressure to curtail the scope of the app.

5.6. Implications for practice and research

5.6.1. Implications for practice

Implications for patients. One focus area of this study was to explore the usefulness of the app. By finding that overwhelming majority of the users found the app useful, this objective is substantiated. Therefore, if such an app is made available to people with thromboembolic conditions who are on Warfarin, they would likely use it as a self-management tool. According to Rowland et al. (2020), disease-related education may hold value for people in remote regions who have limited access to healthcare services, as well as others who need reinforcement. Although the app can help people monitor diet behaviors when on Warfarin, it should be noted that the food choices may need to be tailored for the target population. In this study, for example, there were likely inconsistencies between the food choices offered in the app and what the patients actually ate or what they expected to be among the pool of food items presented. The mHealth app research should continue to focus on knowledge-building and behavioral changes, particularly among socially and economically vulnerable older adults (Lu et al., 2018).

Implications for the clinicians. Generally, Warfarin education for patients are provided verbally and/or with written materials that usually are passive and not sufficient to provide the needed education, especially for illness that patients have to live with for the rest of their lives. Furthermore, patients typically receive intense education in one session. Paper instructions and reinforcement may be appropriate for some patients and situations but learning how to manage specific aspects of self-care, such as diet, requires that patients apply what they have learned to their own situation. Therefore, deploying the app online and making it freely available on the patient portal that is easily accessible will be useful for clinicians and patients to provide continuing education.

5.6.2. Implications for policy

As the number of people with chronic multi-morbidities continue to rise, disease management presents a special challenge to the United States (U.S.) healthcare system. Many people, particularly older adults, are increasingly expected to self-manage their chronic conditions. The problem is that teaching self-management skills to patients is particularly challenging due to a number of factors, such as, limited time for patient and provider communication, healthcare providers' reliance on written instructions, patients having multiple papers that may be lost or thrown away, patient literacy, and patients and family members being overwhelmed with discharge procedures and not focused on the teaching material. Therefore, leveraging game apps to educate people on disease management to improve adherence will be a good health policy. The number of mobile health (mHealth) apps is increasing rapidly in recent years and has gained attention because evidence is starting to show that their use can lead to healthier behaviors and better health outcomes (Bene et al., 2019; Fitzgerald et al., 2020; Whitehead & Seaton, 2016). In recent years, major health systems and organizations have embarked on efforts to develop mHealth apps and/or develop standards to govern their use (Rowland et al., 2020).

The recent decision by CVS Health in the United States to fund Sleepio, a personalized digital sleep improvement program based on digital therapeutics for their patients suffering from insomnia is a big step towards integration of mHealth into mainstream healthcare (Rowland et al., 2020). Eventually, mHealth technologies will play a pivotal role in empowering patients with chronic diseases, such as those on anticoagulation therapy, to manage their own health through digitally enabled care pathways while providing additional benefits to healthcare delivery systems (Rowland et al., 2020).

Another important development in the mHealth apps field is the effort to develop safe and effective guidelines for mHealth apps. One such high-profile effort in this arena in the US is an initiative called Xcertia which is jointly led by the American Medical Association, American Heart Association, and Healthcare Information and Management Systems Society (HIMSS). The aim of Xcertai is to develop standards for the operability, privacy, security and content of mHealth apps (Mathews et al., 2019).

5.6.3. Recommendations for future research

It is likely that some Warfarin use will continue despite the development of new blood thinners. Thus, the diet part of Coumadin Hero will remain relevant. If there were to be further development of this app or an app like it, the multiple limitations identified above need to be addressed. These also may be regarded as recommendations for others considering app development.

Apps should be developed with software that allows easy changes and updates. Customized features like avatars should be made available. The Vitamin K content would also need updating. Additional specificity about how Vitamin K foods are cooked and a broader array of foods that are relevant to particular groups should be added. Likewise, oils, dietary supplements, herbs and alcoholic beverages that are known to have antiplatelet effects should be incorporated. Lastly, the other modules – safety, medication interactions and INR testing – could also be developed and provide users with a broader range of games.

In further app and usability testing, the design limitations of this study should be addressed. That includes using a larger sample size that is more representative of the overall population. Using a Think Aloud approach in an engaged sample would likely identify other design issues. In addition, including heuristics evaluators with similar characteristics as the patients to optimize design features and functionality. The app could be developed to include a pre-game survey questionnaire aimed at collecting information on user characteristics that could be used to customize the app and give the user the option to indicate their preferences, such as avatar, language, common foods they usually buy from local grocery store or farmer's market, and the option to choose less than fifth grade level of app readability.

Lastly, once the app content was optimized and the usability of the app tested, conducting a repeated measures study design to examine the effectiveness of the app would be useful. It is unknown whether patients would use the app and how often. More importantly, it would be useful to know if patients make different food choices based on the knowledge gained.

5.7. Conclusions

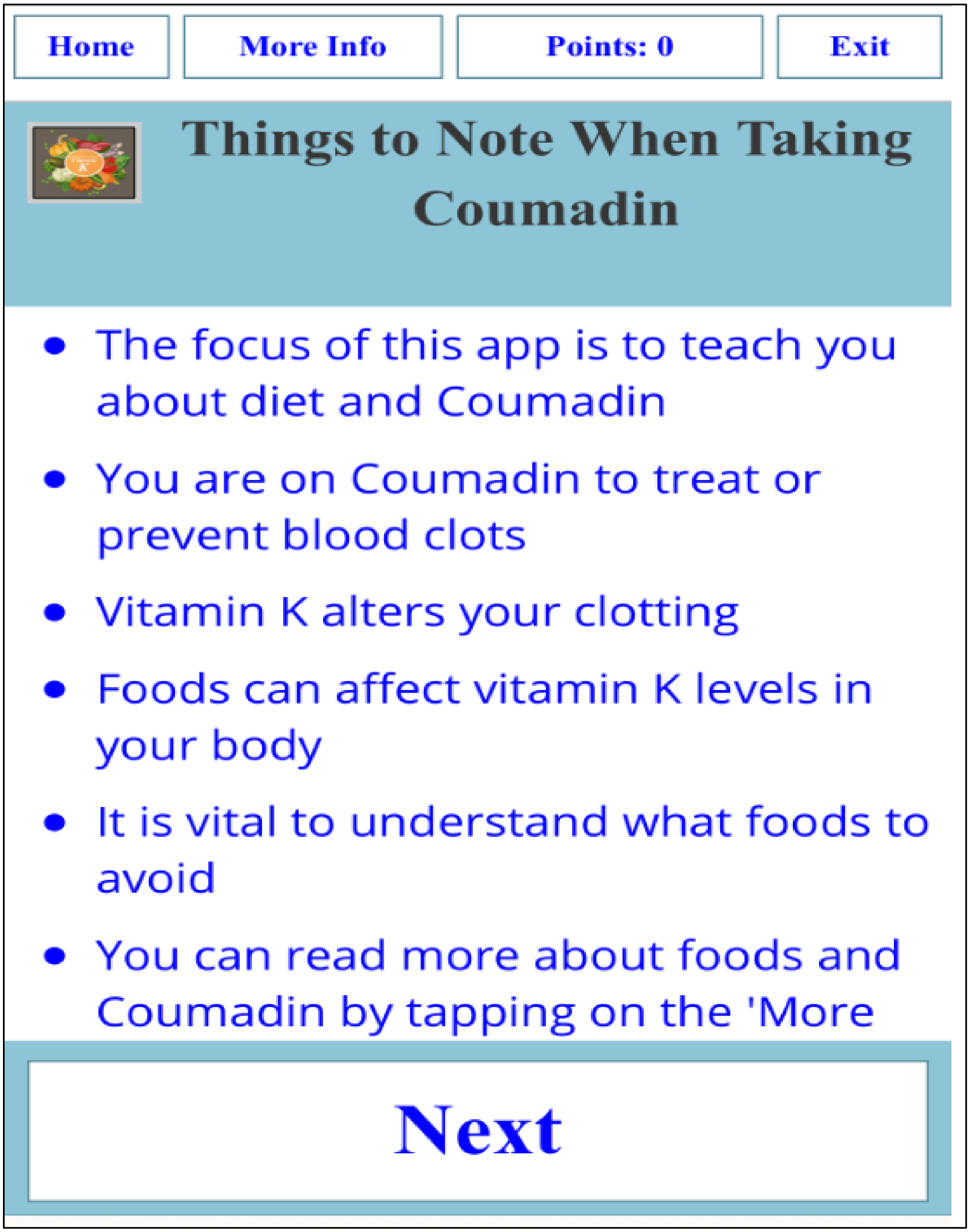
This study involved both the development of the Coumadin Hero app and testing it in a small sample of Warfarin users. This proof of concept study was undertaken to determine the usefulness of an app based on gamification principles to help patients on Warfarin self-manage one aspect of their care – Vitamin K relevant food intake. Since it is well documented that the majority of the people with chronic thromboembolic conditions need to self-manage (Dye et al., 2018; Coleman, 2010; Singh et al., 2016; Wilson & Mayor, 2005), a small change, such as the introduction and adoption of an app as a tool to facilitate self-management could have significant positive impact on people's health.

One focus of this study was to explore the usefulness of the app. By finding that the overwhelming majority of the users found the app useful and indicated that they would use it if the app was available, reinforces people's interest in such tools. Furthermore, the finding that users did not know certain Vitamin K foods and few scored correctly in their first attempt, supports the need for reinforcement.

Appendices

Appendix A: Coumadin Hero Screenshots

Appendix A-1: Game Instructions – Screen 1



Appendix A-2: Game Instructions – Screen 2

Home | **More Info** | **Points: 0** | **Exit**

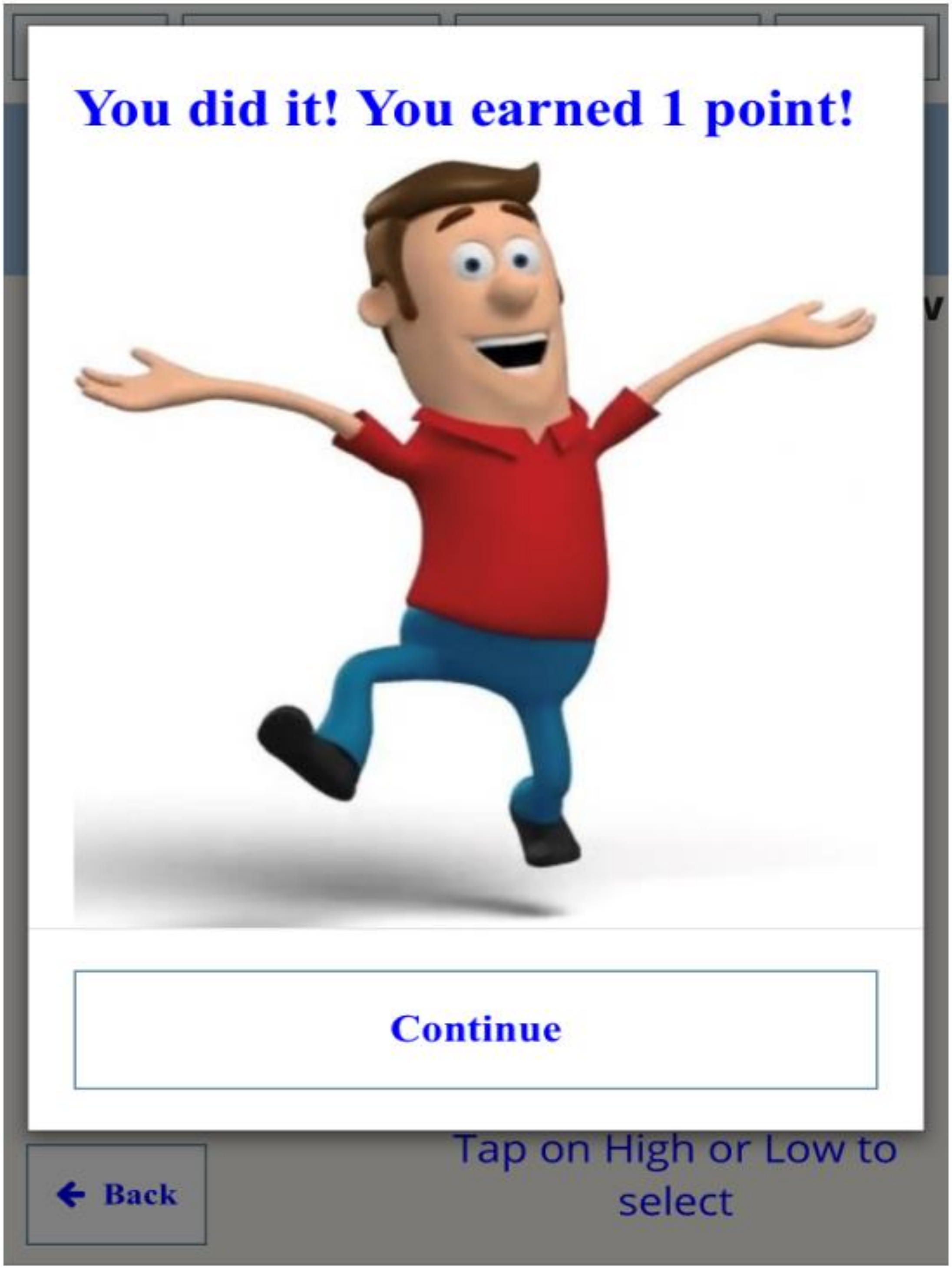
Game Instructions

- You will select the level of Vitamin K for each food shown
- Tap the HIGH or LOW to indicate the level of Vitamin K
- You earn one (1) point per correct answer
- You have 10 minutes to earn 10 points. The game session ends after 10 minutes.
- You have sixty seconds (1 minute) to make a selection when a food is presented

Back | **Play**

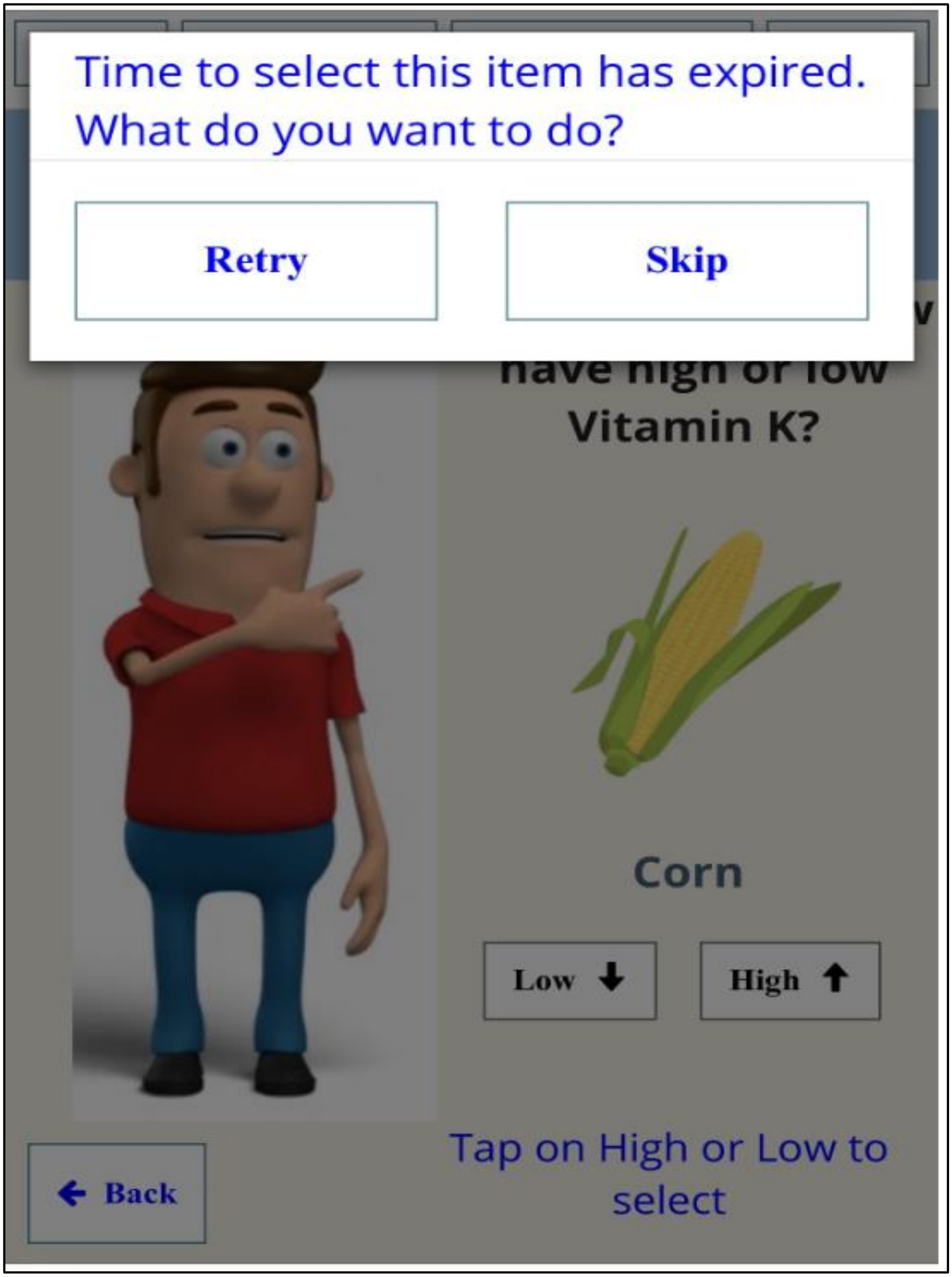
Appendix A-3: Gameplay screen 1 (showing broccoli)

Appendix A-4: Positive Feedback for Correct Response



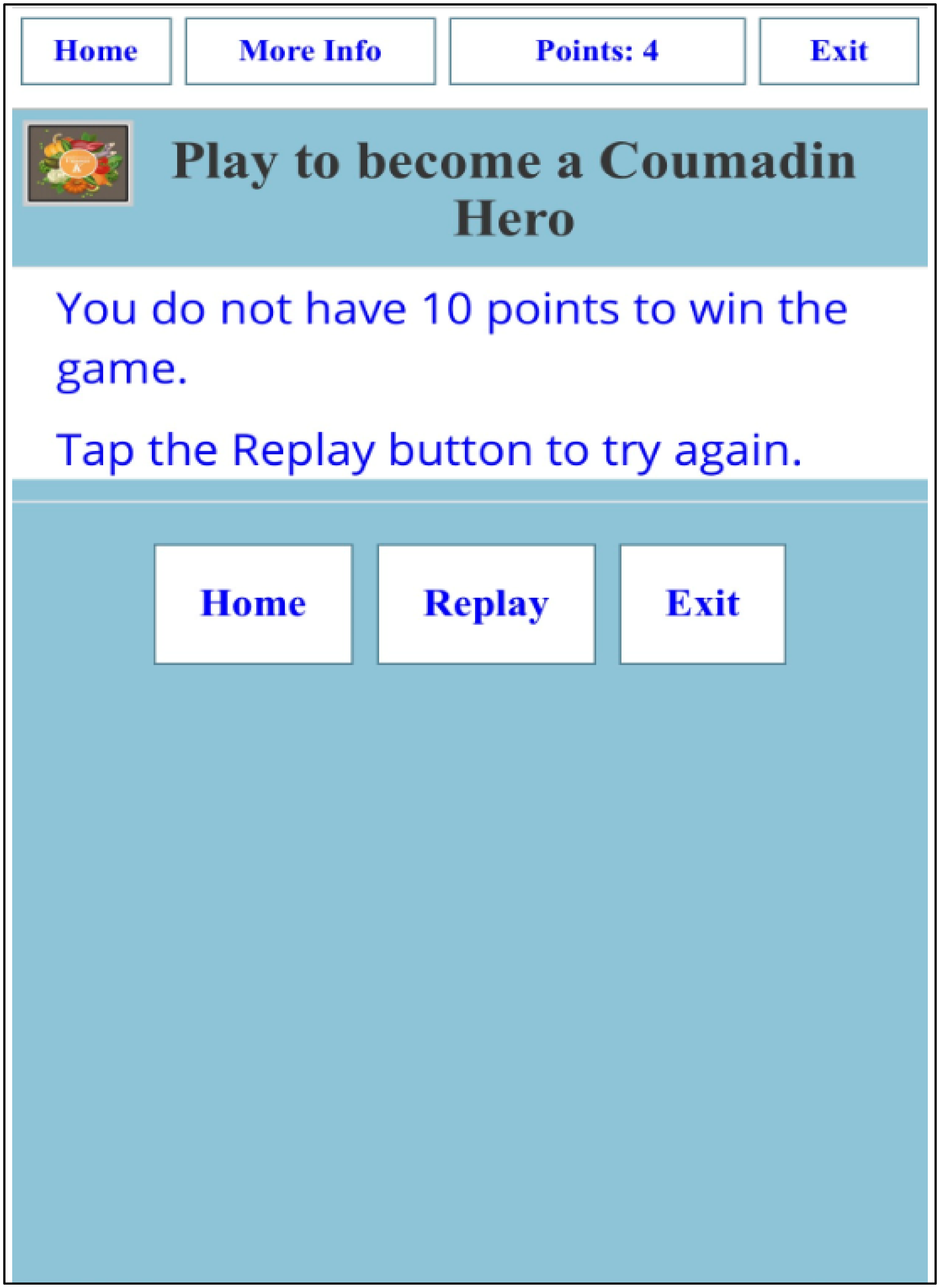
Appendix A-5: Negative Feedback for Incorrect Response

Appendix A-6: Retry or Skip Option for User



Appendix A-7: The Winner's Trophy

Appendix A-8: Unsuccessful Play Attempt



Appendix B: Heuristics/Usability Testing for Mobile Health Game: Guide for Evaluators

Dear Participants,

Thank you in advance for generously volunteering your time to participate in this usability testing. Your input will be invaluable in the development of the game application (called *Coumadin Hero*). I know that your input and feedback will help me build a better product. Thank you again, and do not hesitate to contact me or my advisors Drs. Meg Johantgen and Eun-Shim Nahm if you have questions/comments.

Purpose of the Evaluation

In this evaluation we ask experts in healthcare information technology/informatics to evaluate the usability of the program based on selected usability heuristics (principles). The findings will be used to improve the redesign of the program to correct usability issues identified.

Program: *Coumadin Hero* (Mobile game app)

This is a mobile game app program to help educate people on Warfarin, especially making them aware of foods with high levels of vitamin K. It is expected that users will be able to use the game as an education tool and understand that Vitamin K is an essential part of the body's clotting process and can interfere with Warfarin's effectiveness as an anticoagulant. The target users of the game are adults over 18 years newly prescribed Warfarin. However, it is anticipated that most users will be 65 years and older. The game is called *Coumadin Hero*, which consists of three mini-games: *1. Diet – Vitamin K Foods, 2. My Other Medications, and 3. Blood Clotting testing*. For this heuristic testing, the focus is only on the *Diet- Vitamin K Foods* game, so your responses to the post-game questionnaire should be related to this game.

Instructions

- **Launching the game:** Please use this link<https://Coumadin-hero.firebaseapp.com>to launch the game. You must play the game on an iOS mobile platform (iPhone or iPad). However, the game works on a computer with Internet Explorer or Google Chrome browsers. If you are not an iPhone/iPad user, I have some available to be used for testing. The landing page of the app will open with three mini-games (tap to select the *Diet* game icon/link).
- **Scope**: There are instructions in the app to guide you through the gameplay scenarios. The game instructions are embedded in the game, and it is purposefully done to focus the attention of users to the gameplay without distractions.
- **Selected food items:** For your reference, I have attached a separate sheet of selected food items and corresponding Vitamin K levels. You may use this as a guide to make specific selections.
- **Post-game questionnaire:** As a knowledgeable clinician and an app user, please use the adaptation of Nielsen's (1993) heuristics checklist on the following page, indicate your level of agreement or disagreement with each statement/item on a scale of 1-5 (1 = strongly disagree, 5=strongly agree). For items that are not applicable, use NA. Please do this manually or electronically, using this document, adding comments (if desired) by typing in the comment fields. Please use the last two questions (23 and 24) to tell me what you like about the game and how I can improve the game.

Table B-1: Heuristics evaluation checklist

	Heuristic Group	Rating Strongly Disagree / Disagree / Neutral / Agree / Strongly agree	Comments
#	**Appearance/Aesthetics**	1 2 3 4 5 NA	
1	Primary goal/purpose of game is clear	□□□□□□	
2	The design of the landing page is and simple	□□□□□□	
3	The game icons/links have attractive color scheme	□□□□□□	
4	Appropriate use of white space in the game rules and instructions texts	□□□□□□	
5	Text and colors of the game scenarios are consistent and appropriate for the intended users.	□□□□□□	
6	The food images are meaningful, easily identified, and serve a purpose.	□□□□□□	
	Content		
7	Major headings of the game rules and scenarios are easy to understand	□□□□□□	
8	Easy to find what you need about the game	□□□□□□	
9	The gameplay screen has minimal text/ information presented	□□□□□□	
10	No jargons used	□□□□□□	
11	The game links are clear and follow conventions	□□□□□□	
12	The blinking scenario instructions sticker is appropriate	□□□□□□	
	Navigation		
13	Navigation and controls (buttons/links) are consistent	□□□□□□	
14	Easy to identify your location on the game (breadcrumbs, headers, colors)	□□□□□□	
15	Names of buttons are appropriate and meaningful.	□□□□□□	
16	Parsimonious use of buttons on each screen.	□□□□□□	
	Ease of Use& Satisfaction		
17	Overall, I'm satisfied with how easy it is to use the app/play the game	□□□□□□	

18	It was easy to learn to use the app		
19	The app gives messages that clearly tell me what I did wrong and how to leave the unwanted state without going through an extended dialogue.	□□□□□□	
	General		
20	The "More Info" on Warfarin patient education information is very useful.	□□□□□□	
21	The game play experience might be valuable to the intended users (adults 65 years and older)	□□□□□□	
22	The information presented is likely to increase users' awareness of how diet affect Warfarin therapy	□□□□□□	

23. In a few words, please describe what you like most about the app/game

24. Please, suggest any improvements you would like to see in the redesign/upgrade of the app/game.

Source: Nielsen, J. (1993). *Usability engineering*. San Francisco, Calif: Morgan Kaufmann.

Table B-2: Heuristics evaluation ratings by 3 usability experts

	Heuristic Group	Respondent			
		Expert 1	Expert 2	Expert 3	Mean score
1	Primary goal/purpose of game is clear	5	4	4	4.3
2	The design of the landing page is clear and simple	5	4	4	4.3
3	The game icons/links have attractive color scheme	4	5	3	4.0
4	Appropriate use of white space in the game rules and instructions texts	4	5	3	4.0
5	Text and colors of the game scenarios are consistent and appropriate for the intended users.	3	4	3	3.3
6	The food images are meaningful, easily identified, and serve a purpose.	5	5	4	4.7
7	Major headings of the game rules and scenarios are easy to understand	5	5	3	4.3
8	Easy to find what you need about the game	5	4	3	4.0
9	The gameplay screen has minimal text/ information presented	5	5	2	4.0
10	No jargon used	5	5	4	4.7
11	The game links are clear and follow conventions	4	4	2	3.3
12	The blinking scenario instructions sticker is appropriate	2	4	1	2.3
13	Navigation and controls (buttons/links) are consistent	5	4	2	3.7
14	Easy to identify your location on the game (breadcrumbs, headers, colors)	5	4	3	4.0
15	Names of buttons are appropriate and meaningful.	5	5	3	4.3
16	Parsimonious use of buttons on each screen.	5	5	N/A	5.0
17	Overall, I’m satisfied with how easy it is to use the app/play the game	5	4	3	4.0
18	It was easy to learn to use the app	5	5	3	4.3

19	The app gives messages that clearly tell me what I did wrong and how to leave the unwanted state without going through an extended dialogue.	5	3	4	4.0
20	The "More Info" on Warfarin patient education information is very useful.	5	4	4	4.3
21	The game play experience might be valuable to the intended users (adults 65 years and older)	5	4	4	4.3
22	The information presented is likely to increase users' awareness of how diet affects Warfarin therapy	4	4	4	4.0

1 – Strongly disagree. 2 – Disagree. 3 – Neutral. 4 – Agree. 5. Strongly agree

Table B-3: Issues identified through heuristics evaluation by 3 usability experts

	Heuristic Group	Respondent			
		Expert 1	Expert 2	Expert 3	Mean score
1	Primary goal/purpose of game is clear		I think it could be more clearly stated.		4.3
2	The design of the landing page is clear and simple		Maybe too simple. Reminds me of an old website which may be fine for the target population, but maybe not younger patients.		4.3
3	The game icons/links have attractive color scheme	Almost too bright			4.0
4	Appropriate use of white space in the game rules and instructions texts	The background, example the page of 'things to note' seems almost harsh to the eye with the white background and black fonts bolded.	Might be nice if you didn't have to scroll down, but I understand the audience may need a larger font. Maybe have a flashing arrow to denote there is more text?		4.0
5	Text and colors of the game scenarios are consistent and appropriate for the intended users.	I think the flashing instructions are a distraction and if they could not flash or cover up any of the food items that would be clearer.	Flashing on directions when putting food on plate is distracting. It is also hard to read because it flashes quickly. Also obscures the navigation buttons at the top of the page.		3.3
6	The food images are meaningful, easily identified, and serve a purpose.		The icon on the first page appears to be all vegetables, and some of the text in the directions mentions vegetables, so when I got to the actual game, I was confused a bit to see the "Liver", it just seemed out of place. Probably not a big deal, but something I notices.		4.7
7	Major headings of the game rules and scenarios are easy to understand				4.3

8	Easy to find what you need about the game		Flashing on directions when putting food on plate is distracting. It is also hard to read because it flashes quickly. Also obscures the navigation buttons at the top of the page.	This item is written incorrectly – I would advise revising the wording to state what you are asking about.	4.0
9	The gameplay screen has minimal text/ information presented	I mentioned above the flashing instructions are a distraction and pull the eye while one is looking at what they are working with	Yes, but the flashing banner is distracting and covers information.	The flashing header is confusing and detracts from the purpose of engaging the player	4.0
10	No jargon used			Jargon in singular unless preceded by a quantifier	4.7
11	The game links are clear and follow conventions		The “play” button is named 2 different ways on each screen. I would be consistent.	I’m not sure I know what you mean about ‘game links’ but I selected the ‘more info’ tab and couldn’t get back and the option on the buttons is too lengthy and not clear. 5	3.3
12	The blinking scenario instructions sticker is appropriate	As I mentioned before the blinking to my eye is problematic.		It detracts from the purpose	2.3
13	Navigation and controls (buttons/links) are consistent				3.7
14	Easy to identify your location on the game (breadcrumbs, headers, colors)		Flashing on directions when putting food on plate is distracting. It is also hard to read because it flashes quickly. Also obscures the navigation	There was a header navigation bar but no breadcrumbs. That said I did	4.0

			buttons at the top of the page. The flashing banner is distracting and covers information.	this in a browser because it didn't work on my iPhone	
15	Names of buttons are appropriate and meaningful.			It was hard to determine what the navigation button were or even where they were?	4.3
16	Parsimonious use of buttons on each screen.			I don't know what this item is asking me	5.0
17	Overall, I'm satisfied with how easy it is to use the app/play the game	In fact, could be so easy that users may not use it more than once or twice.			4.0
18	It was easy to learn to use the app			Easy to comprehend but the functions didn't work properly so I can't say it was easy to use	4.3
19	The app gives messages that clearly tell me what I did wrong and how to leave the unwanted state without going through an extended dialogue.		When I select the wrong food, it is not clear which food is wrong. I think that may be helpful considering the population. Also, I noticed when I chose 2 wrong items there was still a green circle, instead of two red circles.	Flashing at me is not helpful	4.0
20	The "More Info" on Warfarin patient education information is very useful.		I thought it was easy to understand. Although, I would recommend that not all text be bolded.	The content needs to be written in a way that more accessible. I'd suggest you link to the AHRQ materials on the subject or to the Mayo Clinic page as both are really well done so	4.3

				why recreate the wheel9	
21	The game play experience might be valuable to the intended users (adults 65 years and older)		I think so, but there may be a learning curve if they are not used to playing games on their smart phone. Did you consider using iPads? More screen real estate.	Only if it works correctly, otherwise it'll may frustrate the user and circumvent the purpose of learning anything	4.3
22	The information presented is likely to increase users' awareness of how diet affects Warfarin therapy			Potentially yes, very much so 11	4.0
23	In a few words, please describe what you like most about the app/game		The ease of use. The font was pleasing. The information presented was simple and easy to understand. I liked that I could drag the foods which made it more interactive than just say selecting a checkbox or a word from a list.		Free text
24	Please, suggest any improvements you would like to see in the redesign/upgrade of the app/game.	It is straight forward and easy to understand.	The flashing banner is annoying/distracting. I would make it static or make the duration between flashes longer. Possibly consider giving feedback when the food is place on plate. Maybe a large X or check mark. Also, see my comments for further suggestions.	10	Free text

Appendix C: Participants' Demographic Questionnaire

1. Age
   ☐ 50–59 years ☐ 60–69 years

2. Gender
   ☐ Male ☐ Female ☐ Not disclosed

3. Marital status
   ☐ Married ☐ Not married ☐ Divorced ☐ Widowed

4. Ethnicity
   ☐ Black/African American ☐ White ☐ Hispanic ☐ Asia ☐ Other

5. Education
   ☐ Less than high school ☐ High school and above ☐ College

6. Living situation
   ☐ Living with family ☐ Living alone ☐ Living in facility

7. Profession
   ☐ Employed ☐ Retired

8. Insurance status
   ☐ Insured ☐ Uninsured

9. Check if you have been diagnosed with any of these disease conditions (past and present)
   ☐Stroke
   ☐ DVT
   ☐ Blood clot in the lung
   ☐ Diabetes
   ☐ Hypertension
   ☐ Arthritis
   ☐ Heart failure
   ☐ Atrial fibrillation
   ☐ Lupus
   ☐ Cancer

10. Years taking blood Warfarin
    ☐ Less 1yr ☐ More than 1yr ☐ Never

11. Ever forgotten taking blood Warfarin?
☐Yes ☐ No ☐ I don't recall

12. Will this be your first time taking Warfarin?
☐Yes ☐ No ☐ I don't recall

Appendix D: Computer Literacy and Technology Usage (Georgsson and Staggers, 2016)

1.How do you consider your level of computer or information technology knowledge?
☐High ☐Medium ☐Small
☐None

2. How often do you use a computer?
☐Everyday ☐ Several times a week ☐Once in a while
☐Never

3. How often do you use the Internet?
☐Everyday ☐Several times a week ☐ Once in a while ☐ Never

4. How do you consider your mobile phone knowledge level?
☐High ☐Medium ☐Small ☐None

5. How often to you use your mobile phone to play video games?
☐Everyday ☐Several times a week ☐Once in a while
☐Never

6. How often do you use your computer to search for health information?
☐Everyday ☐Several times a week ☐Once in a while
☐Never

State whether you agree or disagree with the following statements?

7. I like to use the computer in my leisure time.
☐Strongly agree ☐Agree ☐ Disagree ☐ Strongly disagree

8. Web services, mobile services such as those that support patients within the health care are getting more common. I believe that this is a good thing.
☐Strongly agree ☐Agree ☐ Disagree ☐ Strongly disagree

9. I can see advantages for me personally in using web and mobile services within health care.
☐Strongly agree ☐Agree ☐ Disagree ☐ Strongly disagree

10. What user experiences were you satisfied with regarding the app you just used?

11. What user experiences were you dissatisfied with regarding the app you just used?

Appendix E: Perceived Health Web Site Usability Questionnaire (Nahm et al., 2006).

Satisfaction

We would like to know how satisfied you are regarding the following:
(1 means Very unsatisfied, 7 means Very satisfied)

1. Ease of finding specific information
   1☐ 2☐ 3☐ 4☐ 5☐ 6☐ 7☐

2. Ease of reading the information given
   1☐ 2☐ 3☐ 4☐ 5☐ 6☐ 7☐

3. Overall appearance of screen
   1☐ 2☐ 3☐ 4☐ 5☐ 6☐ 7☐

4. Overall quality of graphics
   1☐ 2☐ 3☐ 4☐ 5☐ 6☐ 7☐

Ease of Use

We would like to know how strongly you agree with the following statements:
(1 means Strongly disagree, 7 means Strongly agree)

5. I found the use of this app easy to learn
   1☐ 2☐ 3☐ 4☐ 5☐ 6☐ 7☐

6. Finding information on the screen requires a lot of mental effort
   1☐ 2☐ 3☐ 4☐ 5☐ 6☐ 7☐

7. Overall, I find this app is easy to use
   1☐ 2☐ 3☐ 4☐ 5☐ 6☐ 7☐

Usefulness

8. Using this app will help me understand specific health problem(s)
   1☐ 2☐ 3☐ 4☐ 5☐ 6☐ 7☐

9. Using this app will help me improve my knowledge about health
   1☐ 2☐ 3☐ 4☐ 5☐ 6☐ 7☐

10. Using this app will help me maintain better health habits.
1☐ 2☐ 3☐ 4☐ 5☐ 6☐ 7☐

Intention to Use

11. I intend to use this app, at least, once a day
1☐ 2☐ 3☐ 4☐ 5☐ 6☐ 7☐

12. I intend to use this app to remind myself of important information
1☐ 2☐ 3☐ 4☐ 5☐ 6☐ 7☐

13. I intend to use this app as guide for health information
1☐ 2☐ 3☐ 4☐ 5☐ 6☐ 7☐

Appendix F: Human Research Protections Office (HRPO) Consent Letter

University of Maryland, Baltimore
Institutional Review Board (IRB)
Phone: (410) 706-5037
Fax: (410) 706-4189
Email: hrpo@umaryland.edu

APPROVAL OF RESEARCH NOTIFICATION

Date: June 21, 2018

To: Mary Johantgen
RE: HP-00078127
Type of Submission: Initial Review
Type of IRB Review: Expedited

Approval for this project is valid from 6/21/2018 to 6/20/2019

This is to certify that the University of Maryland, Baltimore (UMB) Institutional Review Board (IRB) approved the above referenced protocol entitled, "*Development and Usability Testing of a Mobile Health Game for Older Adults on Coumadin*".

The IRB has determined that this protocol qualifies for expedited review pursuant to Federal regulations 45 CFR 46.110, 21 CFR 56.110, & 38 CRF 16.110 category(ies):
(6) - Collection of data from voice, video, digital, or image recordings made for research purposes.

(5) - Research involving materials (data, documents, records, or specimens) that have been collected for any purpose, or will be collected solely for non-research purposes.

(7) - Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

The IRB made the following determinations regarding this submission:
- Written informed consent is required. Only the valid IRB-approved informed consent form(s) in CICERO can be used.
- A waiver of HIPAA authorization for release of the PHI identified in the CICERO application has been reviewed and approved for recruitment purposes only.

This study is approved to enroll 30 local participants.

This study is approved to enroll 30 worldwide participants.

Below is a list of the documents attached to your application that have been approved:
Eligibility Checklist for HP-00078127 v4-10-2018-1523387186540
HIPAA HP 78127.doc
Draft_recruitment_script_Ernest.docx
information sheet.docx
Combined_Demographic_Computer_Use_Survey_Questionnaire_Ernest.docx

1 of 2

citiCompletionReport_Certificate Matthew.pdf
citiCompletionReport_Certificate Ernest.pdf

In conducting this research you are required to follow the requirements listed in the INVESTIGATOR MANUAL. Investigators are reminded that the IRB must be notified of any changes in the study. In addition, the PI is responsible for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103(4)(iii)). The PI must also inform the IRB of any new and significant information that may impact a research participants' safety or willingness to continue in the study and any unanticipated problems involving risks to participants or others.

DHHS regulations at 45 CFR 46.109 (e) require that **continuing review** of research be conducted by the IRB at intervals appropriate to the degree of risk and **not less than once per year.** The regulations **make no provision for any grace period extending the conduct of the research beyond 6/20/2019.** You will receive continuing review email reminder notices prior to this date; however, it is your responsibility to submit your continuing review report in a timely manner to allow adequate time for substantive and meaningful IRB review and assure that this study is not conducted beyond **6/20/2019**. Investigators should submit continuing review reports in the electronic system at least six weeks prior to this date.

Research activity in which the VA Maryland Healthcare System (VAMHCS) is a recruitment site or in which VA resources (i.e., space, equipment, personnel, funding, data) are otherwise involved, must also be approved by the VAMHCS Research and Development Committee prior to initiation at the VAMHCS. Contact the VA Research Office at 410-605-7000 ext. 6568 for assistance.

The UMB IRB is organized and operated according to guidelines of the International Council on Harmonization, the United States Office for Human Research Protections and the United States Code of Federal Regulations and operates under Federal Wide Assurance No. FWA00007145.

If you have any questions about this review or questions, concerns, and/or suggestions regarding the Human Research Protection Program (HRPP), please do not hesitate to contact the Human Research Protections Office (HRPO) at (410) 706-5037 or HRPO@umaryland.edu.

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